

TEG[®] 6s

User manual

CE



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Chapter 1

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Overview

Purpose of the manual

The *TEG® 6s User Manual* provides users with the information needed to effectively operate the TEG® Thrombelastograph® hemostasis analyzer using the 6s series analyzer. This manual includes:

- A detailed description of the analyzer.
- Instructions for operating the analyzer and troubleshooting any difficulties.
- Information on how to properly handle and maintain the analyzer.
- Specifications and performance capabilities.

Use this manual in combination with training supplied by qualified Haemonetics personnel.

What is the TEG 6s system?

The TEG Thrombelastograph Coagulation Analyzer TEG 6s Series system consists of the following components:

- TEG 6s analyzer
- Disposable cartridges with preloaded dried reagents
- Service-Maintenance-Settings (SMS) software interface

The TEG analyzer monitors the harmonic motion of a pendant drop of blood in response to external vibration. As the sample transitions from a liquid state to a gel-like state during clotting, the modulus of elasticity and resonant frequency increase. The analyzer measures these variations in resonant frequency during clotting and lysis and displays the results on a touchscreen display.

Disposable cartridges are used for processing whole blood samples. Blood is delivered by transfer pipette or syringe to a small port in the cartridge. Once a sample has been added to the cartridge and testing has begun, the sample is inaccessible to the user. The cartridges contain all necessary reagents for performing an assay.

The TEG analyzer has two modes of operation: (1) Stand-alone, and (2) computer-controlled through the network interface. Service-Maintenance-Settings (SMS) software provides the interface for an administrator or qualified service technician to change configuration settings, update, backup, and restore software and data files, and manage analyzer calibration parameters. For more information about the SMS software, consult the *TEG 6s Site Administrator Guide*.

Intended use

The TEG® 6s Hemostasis Analyzer is a non-invasive diagnostic instrument designed to monitor and analyze the coagulation state of a blood sample in

order to assist in the assessment of patient clinical hemostasis conditions. The TEG 6s analyzer is indicated for use with adult patients where an evaluation of blood coagulation properties is desired.

Results from the TEG 6s analyzer should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, other coagulation tests.

Precautions

The operator should be aware of the following precautions:

- Read and understand the entire contents of this manual before operating the TEG analyzer - especially precautionary information and specifications.
- The TEG analyzer is to be operated by qualified personnel only.
- If this equipment is used in a manner inconsistent with this manual, protections provided by the device may be impaired.
- Use only Haemonetics parts and accessories with the TEG analyzer. Third-party accessories may cause improper performance.
- DO NOT use malfunctioning equipment. Have the unit repaired by an authorized Haemonetics service representative.
- DO NOT place anything other than human blood, plasma or Quality Control (QC) material into a cartridge.
- Upon removal from the TEG analyzer, used cartridges must be immediately disposed of according to local standard operating procedures for the removal of biohazardous material and should not be mixed with non-biohazardous waste.

Customer Service

Clinical training The local Haemonetics representative will provide staff training upon delivery of the TEG system equipment and should be contacted to organize further instruction, if needed.

Repair service Haemonetics maintains a worldwide network of company-trained service representatives responsible for responding to technical needs concerning equipment. If service beyond the routine maintenance and cleaning described in this manual is required, the local Haemonetics representative should be contacted to provide specific instruction.

Preventive maintenance General maintenance procedures should be performed as required. For instructions, refer to “Cleaning and Disinfecting the Analyzer” on page 7-91. Preventive maintenance procedures should be conducted annually to ensure optimal mechanical functioning of the analyzer and are performed by a trained Haemonetics representative.

Product return guidelines If, for any reason, merchandise must be returned to the company, the customer should contact the local Haemonetics representative to arrange for repairs or returns using procedures to ensure proper handling and subsequent analysis. No returns will be accepted without advanced authorization.

Units returned to Haemonetics for repair are subject to biohazard charges if any component is contaminated with blood or blood products.



Warning: Haemonetics products must be properly cleaned and packaged prior to their return. It remains an important responsibility of the customer to reduce potential health hazards by being aware of the risks involved in the shipping, handling and testing of this material.

Symbols

Symbols found in this document

The terms *Note*, *Tip*, **Caution** and **Warning** are used in this manual with the following symbols to emphasize certain details for the operator.



Note: provides useful information regarding a procedure or operating technique when using Haemonetics material.



Tip: provides additional information or an alternate method to perform a task when using Haemonetics material.



Caution: advises the operator against initiating an action or creating a situation which could result in damage to equipment or impair the quality of the test results; personal injury is unlikely.



Warning: advises the operator against initiating an action or creating a situation which could result in serious personal injury to the patient or operator.

Symbols found on the analyzer and packaging

The following symbols may appear on the analyzer, consumables, or packaging:



Electrical and electronic equipment waste (applies to EU only)

Dispose of the device using a separate collection method (according to EU and local regulation for waste electrical and electronic equipment).



Manufacturer (address for)



Batch code



Authorized representative in the European Community (address for)














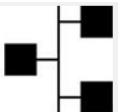
Catalog number



In vitro diagnostic device <ISO>

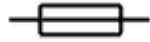


Contains sufficient for <n> tests

	Do not reuse
	Temperature limitation
	Control
	Use by <date>
	Type of venous blood collection tube to be used for the test. Color-coded top conforms to ISO 6710:1995.
	CE mark
	General warning, caution, risk of danger
	Biological risks
	Consult instructions for use
	(Applies to USA only) USA Federal Law restricts the sale, distribution or use of this device to, by or on the order of a physician.
	USB (Universal Serial Bus) port
	Ethernet port



UL listed to Canadian and US standards



Fuse



Direct Current



Power ON/OFF

Indicates a push-push switch, where one position (marked with a line) is on and the other position (marked with a circle) is off.



Serial number



Do not use if package is damaged

Chapter 2

TEG[®] Analyzer Description

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TEG Analyzer Description Overview

This chapter identifies the following main components of the TEG® 6s analyzer system and explains their intended functions.

- Exterior front components
- Exterior back components
- Disposable assay cartridges



Note: Any references made to “front” or “back” are from the perspective of an operator facing the TEG analyzer.

The TEG 6s system consists of an analyzer and disposable assay cartridges. The analyzer contains a user-friendly interface in the form of a color touch-enabled display. Through this interface, the operator can control all operations of the analyzer except turning it on and off, which is accomplished by accessing a switch at the rear of the analyzer. The system is designed to accept a disposable plastic cartridge, into which a blood sample can be placed. Once a test is started, the analyzer processes the sample and reports the results on the touchscreen display.

Exterior Front Components

1. LCD touch screen
2. Cartridge slot



Figure 2-1, TEG analyzer, exterior front components

LCD touch screen

The 6.5" color LCD touchscreen displays instructions that guide the user through TEG analyzer operations. All prompts, directions, selections, and results are displayed on this screen.

Cartridge slot

The cartridge slot at the front of the analyzer accepts TEG analyzer assay cartridges. During a test, the cartridge is locked in place. When the test is complete, a lighted strip flashes around the perimeter of the cartridge slot.

Exterior Back Components

1. Carrying handle
2. Cooling fan with filter
3. USB ports
4. Ethernet port
5. Fuse
6. Power jack
7. On/off switch

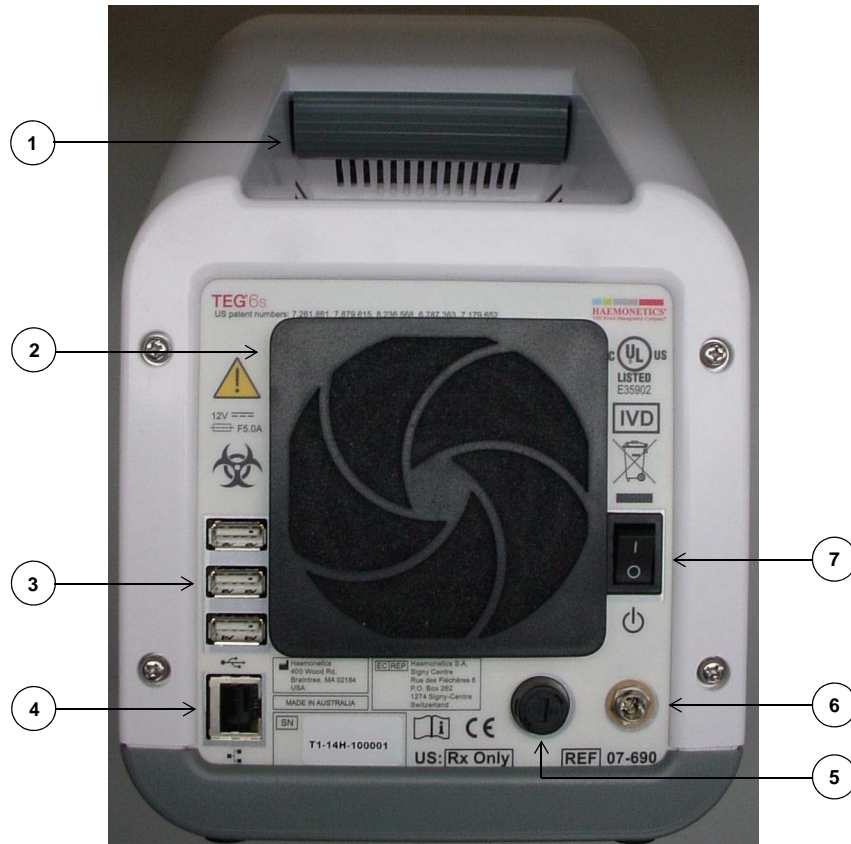


Figure 2-2, TEG analyzer, exterior back view

Carrying handle

The integrated carrying handle is located near the top of the analyzer and allows the unit to be lifted and moved securely.

Cooling fan

The fan on the back of the analyzer ensures that the internal temperature of the analyzer remains close to the ambient temperature. This allows the widest possible range of sample temperatures to be selected without requiring active cooling in the analyzer.

USB ports

Three Standard Type A USB ports are located to the left of the cooling fan and can be used to attach a peripheral device, such as a printer or barcode scanner, to the analyzer.

Ethernet port

The analyzer may be connected via Ethernet cable to a stand-alone computer or Ethernet switch or router for service, maintenance and setup. LED lights on either side of the port have the following functions:

Left LED - Link Speed

- Amber: operating in 1000 BT mode
- Green: operating in 100 BT mode
- Off: operating in 10 BT mode

Right LED - Link Activity

- Blinking green: activity
- Off: no link established

Fuse holder

The fuse holder is a cylindrical housing that protects and holds the fuse.

Fuse

The 250 Volt 5 Amp fuse is located inside the fuse holder on the back of the analyzer.

Power jack

The power jack is located at the back of the analyzer and is the screw-on connection point for the power cord that is supplied by Haemonetics. Do not replace the cord with a substitute. If necessary, contact the local Haemonetics representative for a replacement. Always ensure that the power cord is connected to an appropriately grounded power source (100 - 240 volt 50/60 Hz) per your institution's policy. Use an Uninterruptible Power Supply (UPS) unit between the analyzer and the power source.



Grounding reliability can be achieved only when the analyzer is connected to a properly grounded outlet.

On/Off Switch

The power switch is located at the back of the analyzer. "I" indicates "on" and "O" indicates "off".

Disposable Assay Cartridges

TEG analyzer disposable assay cartridges contain the components needed to perform up to four simultaneous tests from the same blood sample.

Cartridges should be kept in their sealed pouches and in the specified storage conditions (2-8 deg C) until just before use. Cartridges can be used directly from the refrigerator; they do not need to reach room temperature before use.

1. Barcode
2. Sample port

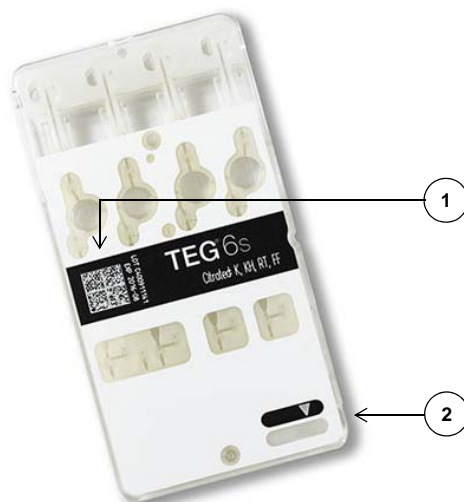


Figure 2-3, TEG analyzer disposable assay cartridge

Sample port

A sample port at one end of the cartridge accepts an unmeasured amount of blood, delivered by transfer pipette or syringe.

Under instrument control, the cartridge pulls the blood sample into up to four staging areas, mixes the sample with reagents that have been dried in place, and then transfers a small amount into the test cells. Excess blood is moved to a sealed waste area within the disposable.

Barcode

The barcode on the cartridge allows the analyzer to identify the cartridge type, test type, expiration date, and lot number.

Cartridge Library

In addition to the barcode on the cartridge, the analyzer system also uses a Cartridge Library file to determine the type of test the cartridge is intended to perform. The Cartridge Library holds information that the analyzer needs to run the appropriate scripts and display the correct parameters for each test. Haemonetics periodically provides updates to the Cartridge Library which can be downloaded to your system.

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Storage and Handling

Safe and successful operation depends in part on the proper routine handling of the TEG[®] 6s analyzer, disposables, and blood samples. The operator should be aware of the problems that could result if these items are stored, installed, or used incorrectly.

Storing and handling the analyzer

Unpacking the TEG analyzer

The TEG analyzer is packaged to reduce the risk of damage during shipment. Remove all polystyrene inserts and carefully remove the TEG analyzer from the box. The power adapter and cables are packaged separately.



Note: Save the shipping box and molded polystyrene inserts. If the TEG analyzer needs to be returned for repair or preventive maintenance, it must be shipped in its original packaging in order to avoid damage. Haemonetics will charge for any repairs necessary due to improper packaging.

Placement of the TEG analyzer

Use the following guidelines to correctly place the TEG analyzer:

- Place the TEG analyzer on a flat surface such as a table or lab bench.
- Proper operation of the analyzer requires adequate airflow through the cooling fan at the rear of the device. Ensure that the fan is not obstructed by proximity to a wall or other equipment.
- Make sure that the device is positioned so that it is easy to reach and to operate the power switch and power cord disconnection.

Storage and handling of the TEG analyzer

The TEG analyzer must be operated at room temperature (10°- 32°C). Although the device can be stored at a temperature between -20°C and +50°C, it must be brought to operating temperature before use. The TEG analyzer is designed for indoor use only.

The operator should wear protective gloves when handling the TEG analyzer.



Caution: *If the TEG analyzer has been stored at a temperature outside the operating temperature range, allow sufficient time for the analyzer to equilibrate to room temperature before use.*



Note: See [“Specifications” on page 88](#) for a complete list of environmental conditions in which to store and operate the TEG analyzer.

Storing and handling the cartridges

The storage and handling of the TEG analyzer assay cartridges and quality controls may differ depending on the type of reagent or control contained within them. Refer to each product insert for storage and handling instructions.

Transporting the analyzer

Before transporting the TEG analyzer from one location to another, ensure that all plugs, cords, and cartridges are removed from the device. The analyzer must also be cleaned and disinfected prior to moving the analyzer to a new location, or for return shipment if servicing is necessary.

Warnings for the Operator

Electrical shock hazards

The TEG analyzer operates at a low-rated voltage. The risk of electrical shock is, therefore, minimal. However, the operator should never remove the analyzer's covers. Maintenance that requires the removal of these covers remains the responsibility of a Haemonetics-trained technician.

Power outlet connection

Do not power the device using a power cord other than the one originally supplied by Haemonetics for the TEG analyzer. Always ensure that the power cord is connected to an appropriately grounded power source per your institution's policy.



Caution: *Grounding reliability can only be achieved when the equipment is connected to a properly grounded outlet.*



Caution: *Do not unplug the male single-pin connector end of the power cord from the analyzer while leaving the power cord connected to a live power source. Electrical shorting and power supply damage may occur.*

Bloodborne pathogens

Users should adhere to Standard Precautions when handling or using this device. All parts of the TEG analyzer system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. Although the TEG analyzer does not present a significant biohazard risk in itself, the unit is used to analyze human blood, so care must be taken to properly handle, clean, and disinfect the equipment as appropriate.



Warning: **Special cleaning needs, such as a blood spill, should be dealt with promptly. Follow local standard operating procedure for blood precautions when cleaning up a blood spill or dealing with blood contaminated components. Dispose of all cleaning materials as biohazardous waste.**

At a minimum, use the following precautions when handling blood and disposing of blood-contaminated material:

- While operating the TEG analyzer, wear powder-free protective gloves and wash hands immediately after removing the gloves.
- Switch gloves between patients and after completion of testing.
- Wear fluid-resistant clothing.

Proper handling of blood contaminated material

Even though the only working surfaces that routinely come into contact with blood are the internal surfaces of the disposable assay cartridge, any TEG analyzer surface that could be contaminated by a blood spill should be properly cleaned and decontaminated with an appropriate disinfectant (see [“Cleaning and Disinfecting the Analyzer” on page 91](#)). This should only need to be done as required by laboratory protocol and immediately after any blood spill.

Precautions must be taken to eliminate or reduce the hazards involved with removing the TEG analyzer from its point of use, transporting it from one place to another, or disposing of the analyzer. If any blood-contaminated material must be returned to Haemonetics for further inspection, see [“Product return guidelines” on page 12](#) for instructions.



Warning: Haemonetics products must be properly cleaned and packaged prior to their return. It remains an important responsibility of the customer to reduce potential health hazards by being aware of the risks involved in the shipping, handling and testing of this material. Units returned to Haemonetics for repair are subject to biohazard charges if any component is contaminated with blood or blood products.

Proper disposal of biologically contaminated materials

Any disposable material used during a procedure is considered to be biologically contaminated and biohazardous. It must be disposed of according to local standard operating procedures for the removal of such material and should not be mixed with non-biohazardous waste.

Handling of glass objects

Glass objects such as blood collection tubes and Quality Control (QC) vials should be handled with care.



Warning: In case of glass breakage, watch for sharp edges.

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Overview

This chapter explains how to get started using the TEG[®] 6s analyzer and includes the following information:

- TEG analyzer design principles - how the analyzer works
- Understanding TEG parameters
- Setting up and logging in to the TEG analyzer
- Exploring the touchscreen and viewing icons
- Viewing test results in a table or tracing
- Changing settings such as the date and time formats

TEG Analyzer Design

Principles of design

The TEG analyzer approach to the monitoring of patient hemostasis is based on the following:

1. The end result of the hemostasis process is the clot.
2. The clot's physical and developmental properties (rate, strength, and stability) affect whether the patient will have normal hemostasis, will hemorrhage or will develop thrombosis.

How the TEG analyzer works

Disposable assay cartridges contain all of the components necessary to allow the analyzer to prepare samples and perform hemostasis tests.

The analyzer automatically draws the blood into the active area of the cartridge, meters the exact amount required for the test, and mixes it with the reagents spotted in the cartridge. The analyzer then monitors the harmonic motion of a pendant drop of blood in response to external vibration. As the sample transitions from a liquid state to a gel-like state during clotting, the modulus of elasticity and resonant frequency increase. The analyzer measures these variations in resonant frequency during clotting and lysis. The results are displayed in a table and on a graphical tracing that reflects a hemostasis profile of clot formation.

The resulting hemostasis profile is a measure of the time it takes for the first measurable clot to be formed, the kinetics of clot formation, the strength of the clot, and the breakdown of the clot, or fibrinolysis.

1. R: Reaction time
2. K: K-time
3. α : Angle
4. MA: Maximum Amplitude
5. LY30: Percent Lysis 30 minutes after MA

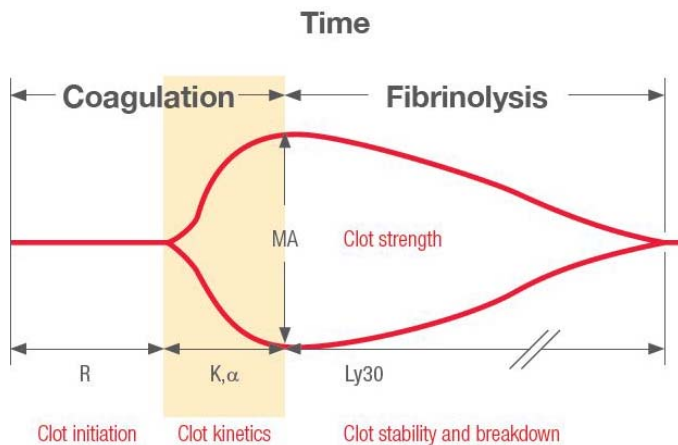


Figure 4-1, TEG tracing parameters

Individual points in the hemostasis profile indicate specific parameters of patient hemostasis. These parameters – R, K, Angle, MA, and LY30 – are indicated in the above diagram. The next section describes the TEG analyzer parameters in more detail.

TEG Analyzer Parameters

The TEG analyzer uses various parameters to determine a clot's properties. These parameters determine clot formation, lysis, kinetics, strength and stability.

The following table lists each parameter and its definition.

Parameter	Description
R	Reaction time. The amount of time between the start of the test and the beginning of coagulation.
K	The speed of formation of the clot from R time to a specific clot strength.
Alpha (Angle)	The speed of clot strengthening.
MA	Maximum Amplitude. The ultimate strength of the clot.
LY30	Percent lysis 30 minutes after MA is finalized. The LY30 measurement is based on the reduction of the tracing area that occurs between the time that MA is measured until 30 minutes after the MA is finalized.
TEG-ACT	Calculates an ACT (Activated Clotting Time) value from the R parameter for RapidTEG™ tests.
FLEV	Calculates a FLEV (Functional Fibrinogen Level) value from the MA parameter for Functional Fibrinogen tests.
% Inhibition	Indicates the reduction in platelet contribution to overall clot strength. Displayed for PlateletMapping tests.
% Aggregation	Indicates the percent of platelets not inhibited, determined by comparing the uninhibited platelet contribution to the baseline platelet contribution. Displayed for PlateletMapping tests.

TEG Analyzer Tests

Haemonetics provides various assay cartridges for use with the TEG analyzer. Refer to the included product inserts for an explanation of the tests, the reagents used, which parameters are measured, and the expected results.

Setting Up and Logging into the Analyzer

Set up the analyzer

In most cases, a Haemonetics representative is responsible for the initial unpacking and setup of the TEG analyzer. The following setup instructions are provided in the event that a repaired analyzer is shipped back to you or that you need to relocate the analyzer.

The analyzer ships with a US power cord that is suitable for use in North America and Japan. Refer to the following table for a list of available Haemonetics power cords.

Region	Description	Part number
Europe	Power cord, AC, 4.6 meters (15 feet)	T1234-00
UK/Ireland	Power cord, 5 meters (16.4 feet)	106770-00
UK/Ireland	Power cord, 2.5 meters (8.2 feet)	85113-00
Switzerland	Power cord, 250V AC, 5 meters (16.4 feet)	85260-200

Unpack the analyzer

1. From the shipping box, remove the small box containing the power supply and extra ferrite clamp.



Note: The ferrite clamp is for installations where an Ethernet cable will be permanently connected to the analyzer. For more information about installing the clamp on the Ethernet cable and setting up a network connection, contact TEG System Technical Support or refer to the TEG 6s SMS Site Administrator Guide (116420-IE).

2. Remove the top foam supports and open the protective plastic bag.
3. Grasp the analyzer by the handle and lift it out of the shipping box.

Position the analyzer

Set up the TEG analyzer in location that is reasonably flat and level, and where the analyzer will be protected from accidental damage. See [“Storing and handling the analyzer” on page 24](#) for complete guidelines on how to correctly place the analyzer.

Connect the analyzer to power

Screw the smaller end of the power cord onto the power jack at the back of the analyzer, and then plug the other end into a grounded wall outlet.



Caution: Always plug the power cord into the analyzer first, then into the wall outlet. This prevents the possibility of electrical shorting or power supply damage.



Note: Haemonetics recommends the use of a UPS (Uninterruptible Power Supply) between the analyzer and the wall outlet. This would allow a test to run to completion in the event of a power loss.

Start the analyzer

To turn on the analyzer, move the power switch at the rear of the analyzer from the "O" position to the "I" position. After a brief startup sequence, an initialization screen appears, and then the device executes a Power-On Self Test (POST).

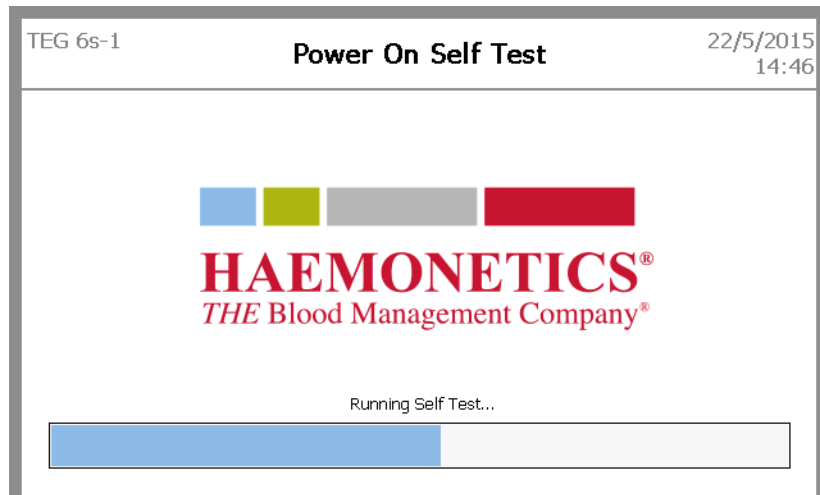


Figure 4-2, Initialization and POST screen


Log into the analyzer

Following a successful POST (see Figure 4-2 above), the login screen displays.



Figure 4-3, Login screen

To log into the TEG analyzer:

1. Using the touch screen keyboard on the *Login* screen, enter your user name in the *Username* box.
2. Move the cursor to the *Password* box by doing one of the following:
 - Touch the *Password* box
 - Touch the return key 
3. Enter your password, and then touch **login**.

If your login attempt fails, the *Username* and *Password* boxes are highlighted in red, as shown below. If this occurs, re-enter your user name and password.

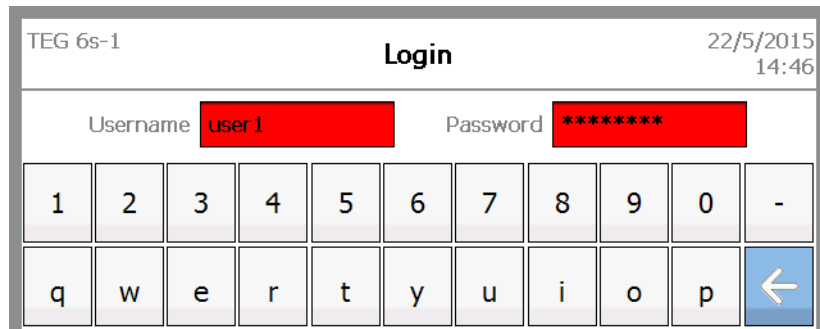


Figure 4-4, Failed login - Username and Password fields highlighted in red

Update your password

When you are logged into the TEG analyzer, you can update your password at any time from the *Settings* screen.

To update your password:

1. From the *Home* screen, touch **settings**.
2. On the *Settings* screen, touch **Update password**.
3. On the *Update Password* screen, in the *Update Password* and *Confirm Password* boxes, enter your new password according to the following criteria:
 - The password cannot contain your user name.
 - The minimum length of the password is 8 characters.
 - The maximum length of the password is 12 characters.
 - The password must contain at least one numeric character or symbol (the special characters “&” and “#” are not accepted).
 - The password cannot be a duplicate of any of your previous eight passwords.

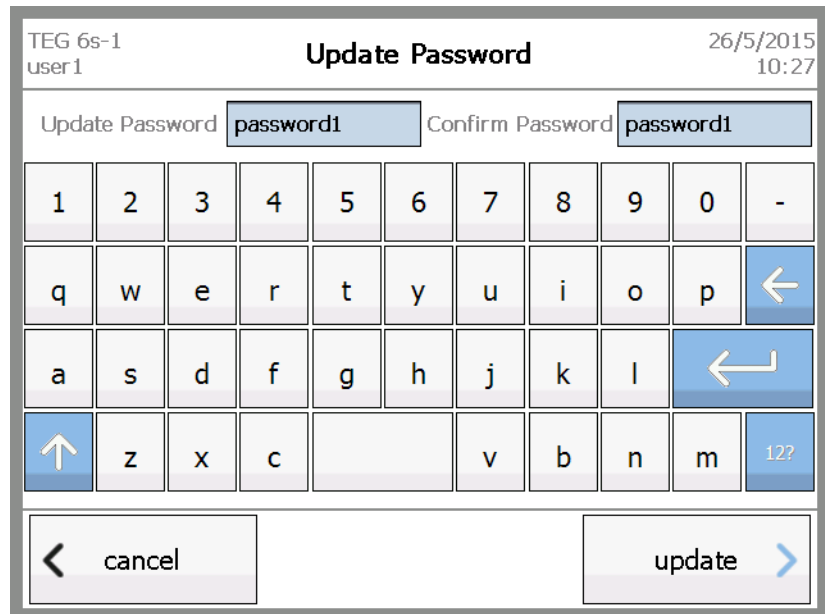


Figure 4-5, Update Password screen

4. Touch **update**.
5. In the password confirmation message, touch **ok**.

Log out of the analyzer

After you log into the analyzer, you can log out at any time from the *Home* screen, by touching **logout** in the lower left corner of the screen. For more information about the *Home* screen, see [“Exploring the Touchscreen” on page 39](#).

Turn off the analyzer

It is safe to turn off the analyzer from the *Login* screen. To do this, move the power switch at the back of the analyzer to the off position.



Note: Make sure that you remove any existing cartridge from the cartridge slot before you turn off the analyzer. When the analyzer is off, a cartridge that remains in the device is clamped with a spring to prevent its removal.

Exploring the Touchscreen

This section provides a brief overview of the screens and icons that are displayed on the TEG analyzer touchscreen.

The touchscreen is designed to be intuitive and easy to use. During all analyzer operations, a button at the lower right of the touch screen takes you forward to the next step of the workflow, while a button at the lower left returns you to the previous step.

On every screen, the device name and username of the person who logged in displays in the upper left corner, and the system date and time displays in the upper right corner.

Home screen

After you log into the TEG analyzer, the *Home* screen appears.

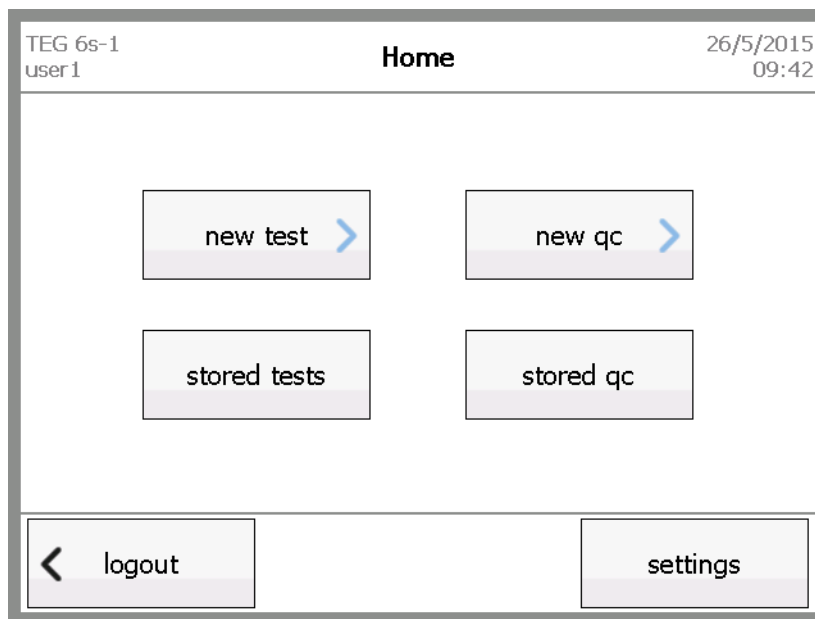


Figure 4-6, Home screen

The *Home* screen displays the main menu for the analyzer. From this screen, you can do the following:

- Start a new patient test or quality control test workflow
- Review results from earlier patient tests or quality control tests
- Access analyzer settings
- Log out of the analyzer

Detailed instructions for these tasks are provided in later sections of this manual.

Icons

Icons at the top of the screen indicate the status of the analyzer, such as whether the device is saving data, is locked, is being accessed by a remote user, or has expired QC.












Note: Errors, critical errors, and warnings are displayed in popup windows. For more information on error messages, see “Errors and Alerts” on page 82.

TEG 6s-1 user 1		QC		4/9/2015 14:24	
L1 Quality Control					validation - run1
4/9/2014 14:08	R (min)	K (min)	Angle (deg)	MA (mm)	
L1	1 0.7-1.7	0.4 0.4-0.6	84.2 77-86	57.1 54-67	
L1	1 0.7-1.7	0.4 0.4-0.6	84.2 77-86	57.5 54-67	
L1	1 0.7-1.7	0.4 0.4-0.6	84.2 77-86	56.8 54-67	
L1	1 0.7-1.7	0.5 0.4-0.6	84.2 77-86	58.4 54-67	
stop		print		tracings	

Figure 4-7, Location of icons in the interface

The following table lists the icons that you may encounter when operating the TEG analyzer, along with their definitions.

Icon	Description
	The analyzer is being accessed by a remote user while a local user is logged in.
	The analyzer is being accessed by a remote user and is locked to prevent a local user logging in.
	Data is being saved.

Icon	Description
	Data is being collected.
	QC overdue. The numbers beside the icon indicate the QC level (L1 and/or L2) that is overdue.
	Test run with QC overdue.
	Error
	Warning
	Critical error
	The Patient test was completed (all parameters finalized). The QC test passed.
	The Patient test timed out before all parameters finalized or an unrecoverable error occurred during the test. The QC test failed.
	The Patient test was stopped before all parameters finalized.

Viewing Test Results

Test results are plotted on a continuously-updated results screen and on a graph (tracing) to allow visual assessment of parameters. Numerical parameters are determined over the course of a test (which can run for a maximum of 90 minutes).

Test results screen

The following illustration identifies the information that appears on the results screen for an in-progress four-channel test.

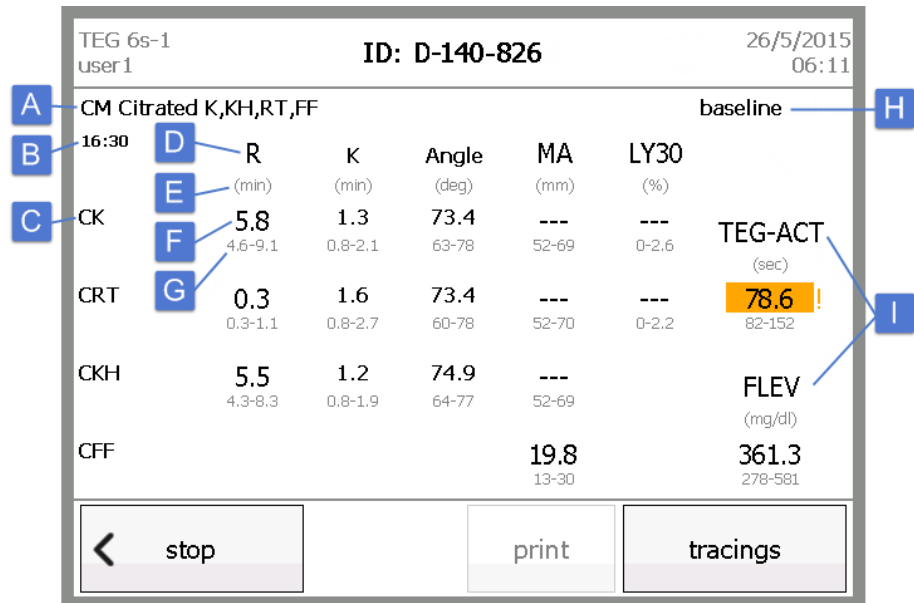


Figure 4-8, Test results screen - parameters

- A. **Cartridge name:** This is the name that appears on the outside of the cartridge.
- B. **Test timer:** The timer begins when the test starts. Once the assay is complete, the timer stops and is replaced by the date and time that the test started.
- C. **Test name:** Each test name – one per channel – is displayed in the left column. You can touch the test name to display the tracing for the test.
- D. **Test parameters:** The top row displays the primary parameters that are being measured for each test.
- E. **Parameter units:** The units of measure are displayed under each parameter name.
- F. **Parameter values:** The large numbers indicate the results of each test. A parameter displays with dashed lines until it is finalized and a numerical result appears. Any parameter that is not used for a test remains blank. If a finalized parameter falls outside of the expected range, it is highlighted in orange and an exclamation mark appears next to the number.

- G. **Reference ranges:** The maximum and minimum limits for normal results for each parameter appear under the parameter values.
- H. **Test information:** The information that is added for the test in the *Test information* screen displays at the top right of the screen.
- I. **Additional parameters:** If additional parameters are calculated for any test, they display in the right column.

Tracing screens

TEG tracings provide information at a glance about running or completed tests. At any time, you can access tracings by touching the **tracings** button on the results screen.

You can view the tracing for a test in three modes: superimposed, offset, and individual-channel. From any tracing screen, touch **next tracing** to cycle through the view modes (see Figures 4-9 to 4-11).

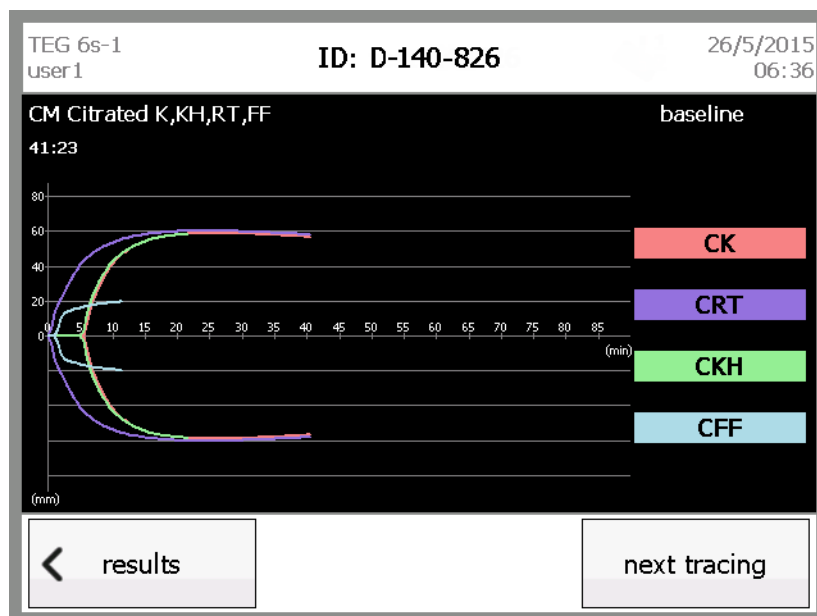


Figure 4-9, Superimposed tracings

Superimposed and individual-channel tracings display a Y axis that indicates the amplitude (in millimeters). All tracing modes display an X axis that indicates the time (in minutes).

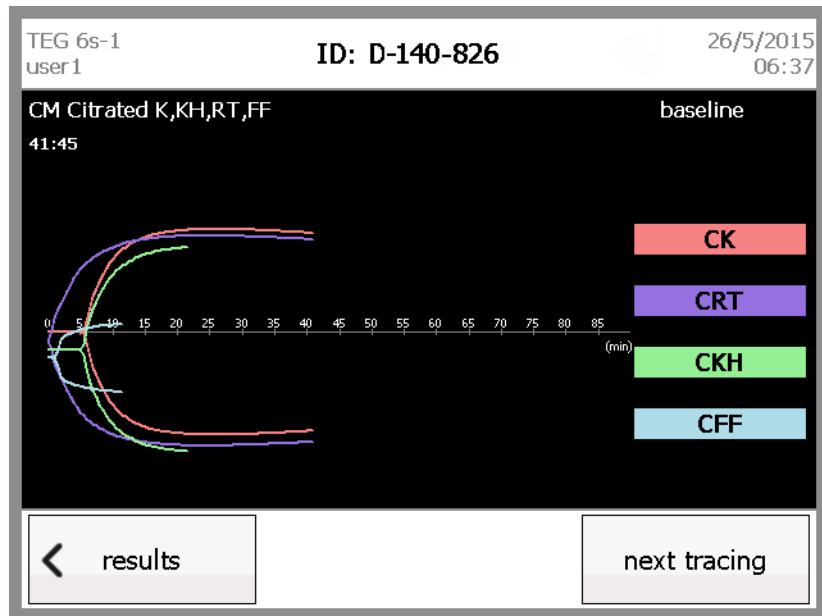


Figure 4-10, Offset tracings

On the right side of the superimposed and offset tracing screens, a legend displays each test name and corresponding color for the tracing. You can touch the test name in the legend to display the individual-channel tracing for the test.

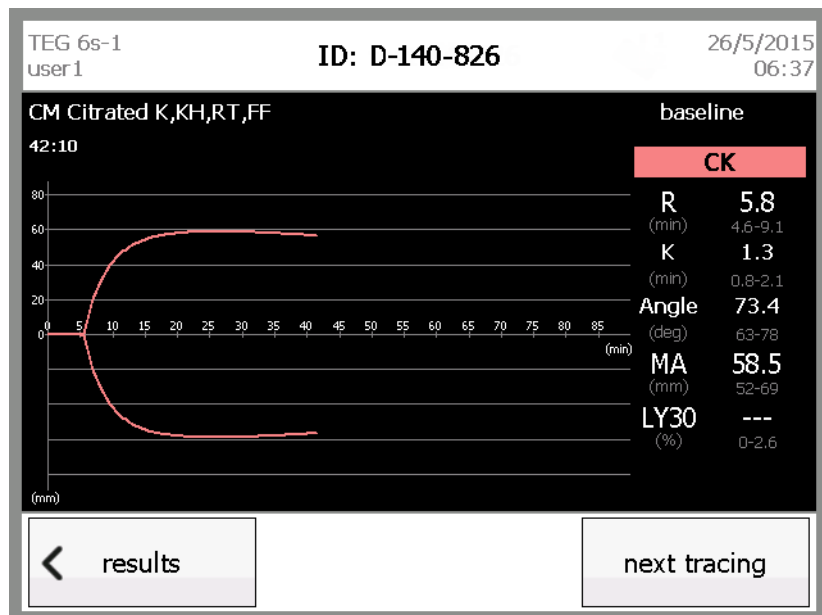


Figure 4-11, Individual-channel tracing

On the right side of each individual-channel tracing, the test name is displayed, along with the parameter names, units, parameter values, and ranges.

Configuring Settings

With Administrator privileges, you can access the *Settings* screen to do the following:

- Configure date and time settings including:
 - Set the current date and time
 - Specify the date and time styles
- Change the time zone
- Configure LAN settings
- View version information and the IP address
- Calibrate the touchscreen



Caution: Make sure that the system date and time are set correctly. The analyzer uses the system date and time to prevent the use of an expired cartridge.



Note: If you do not have Administrator privileges, all functions accessible from the *Settings* screen are read-only except the **update password** function.

Configure date and time settings

From the *Settings* screen, you can set the current date and time and choose the desired style for how the date and time display on all screens.



Notes:

- Altering the date and time settings does not affect previously run tests.
- You must restart the analyzer for date and time changes to take effect.

To configure the date and time settings:

1. Log in as an Administrator, and then on the *Home* screen, touch **settings**. The *Settings* screen displays.

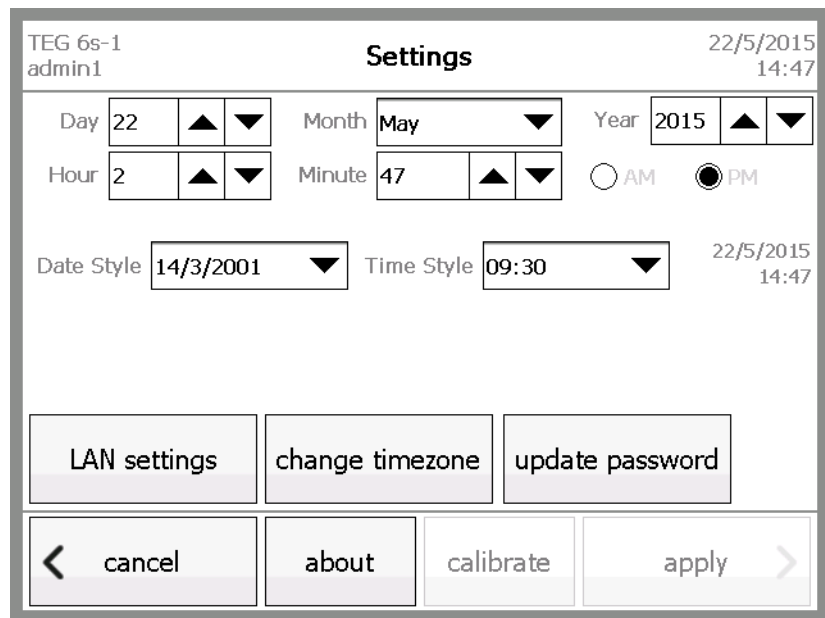


Figure 4-12, Settings screen

2. On the *Settings* screen, touch the up or down arrows for the *Day*, *Month*, *Year*, *Hour*, and *Minute* boxes until the desired setting is displayed.



Note: Each touch of the arrow increases or decreases the value by one.

3. Touch the down arrow for the *Date Style* and *Time Style* boxes and select the desired style for each. An example of the currently selected styles is displayed to the right of the *Time Style* box.
4. Touch **apply**.
5. From the *Home* screen, touch **logout**.
6. Turn the analyzer off and then back on again. Ensure that the system date in the top right corner is correct.

Change the time zone

If necessary, you can change the time zone for your region.

To change the time zone:

1. From the *Settings* screen, touch **change timezone**. The *Change Time Zone* screen displays.

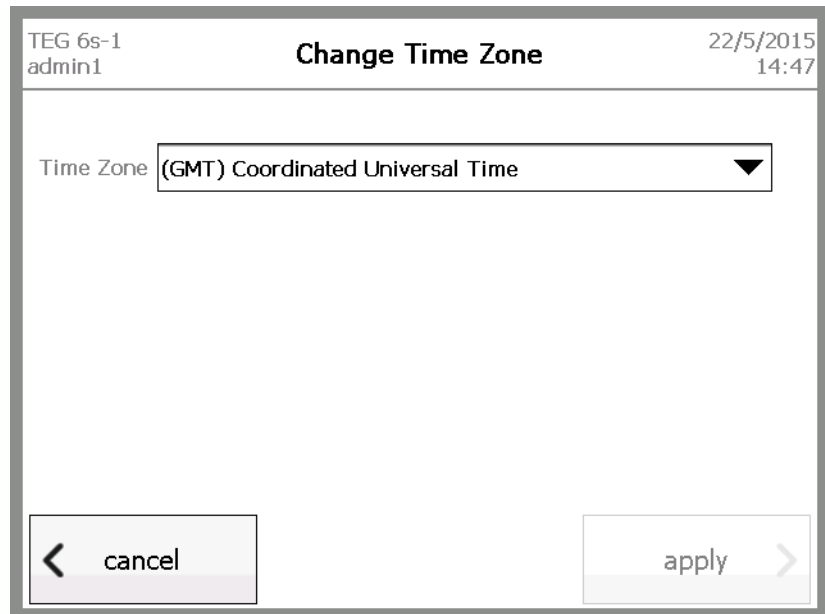


Figure 4-13, Change Time Zone screen

2. Touch the down arrow for the *Time Zone* box to display a list of time zones.

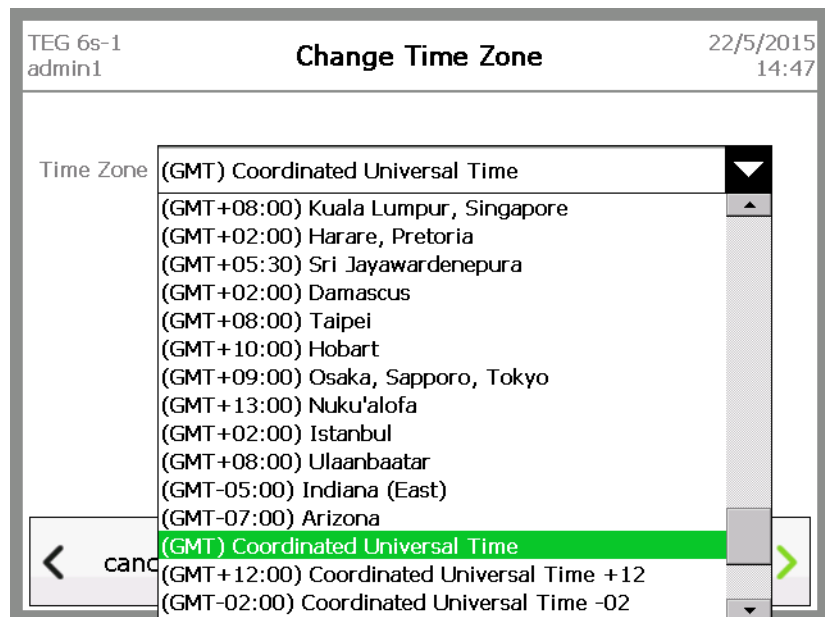


Figure 4-14, List of time zones

3. Select the correct time zone from the list and touch **apply**. A message displays, indicating that you must restart the analyzer for the time zone change to take effect.

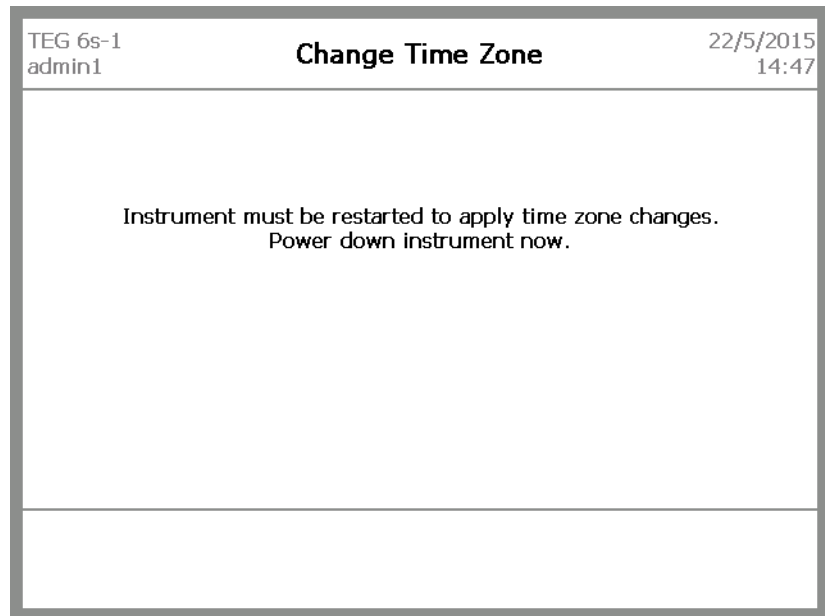


Figure 4-15, Power down message

4. Turn the analyzer off and then back on again.

Configure LAN settings

The *LAN Settings* screen allows you to select how you want the analyzer's IP address to be assigned within the Local Area Network (LAN). In most cases, the *DHCP* (Dynamic Host Configuration Protocol) mode is preferred, allowing the router to assign the IP address and subnet mask. For more advanced network setup, it is possible to select the *Static* mode and configure a static IP address and subnet mask. For more information, contact your network administrator.



Note: You must restart the analyzer for LAN setting changes to take effect.

To configure the analyzer's LAN settings:

1. From the *Settings* screen, touch **LAN settings**. The *LAN Settings* screen displays.

TEG 6s-1
admin1

22/5/2015
14:47

LAN Settings

Mode DHCP Static

IP Address 192 ▲ ▼ . 168 ▲ ▼ . 0 ▲ ▼ . 21 ▲ ▼

Net Mask 255 ▲ ▼ . 255 ▲ ▼ . 255 ▲ ▼ . 0 ▲ ▼

Figure 4-16, LAN Settings screen

2. Do one of the following:

If you want to...	Then:
Allow the router to assign the IP address and subnet mask	<ol style="list-style-type: none"> a. Next to <i>Mode</i>, select <i>DHCP</i>. b. Touch apply.
Configure a static IP address and subnet mask	<ol style="list-style-type: none"> a. Next to <i>Mode</i>, select <i>Static</i>. b. Next to <i>IP Address</i>, touch the up or down arrows to enter the desired values. c. Next to <i>Net Mask</i>, touch the up or down arrows to enter the desired values. d. Touch apply.

3. From the *Home* screen, touch **logout**.
4. Turn the analyzer off and then back on again.

Calibrate the touchscreen

Haemonetics recommends that the touchscreen be calibrated upon first use or installation. This ensures that the touch screen responds in the correct place. It should not be necessary to calibrate the touchscreen more than once in the lifetime of the analyzer.

To calibrate the touchscreen:

1. From the *Settings* screen, touch **calibrate**.
2. On the calibration screen, carefully touch and briefly hold a stylus on the center of the target marked on the screen. Repeat this process as the target moves around the screen.

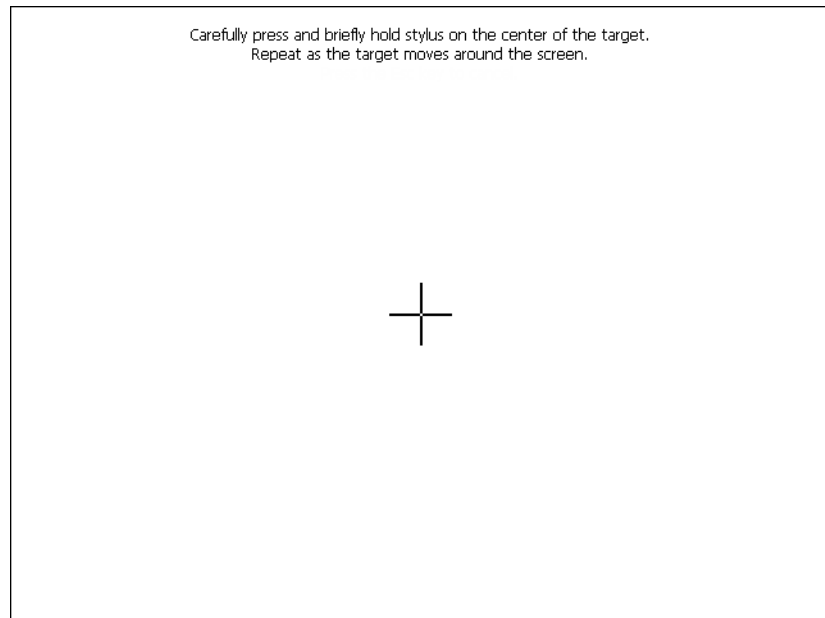


Figure 4-17, Calibration screen

3. When no further targets are displayed, tap anywhere on the screen to save the calibration and return to the *Settings* screen.

View information about the analyzer

To view information about the analyzer:

1. From the *Settings* screen, touch **about**.
2. On the *About* screen, view information such as the version of the software currently installed on the analyzer, serial number, IP address, and the date and time that QC was last run.

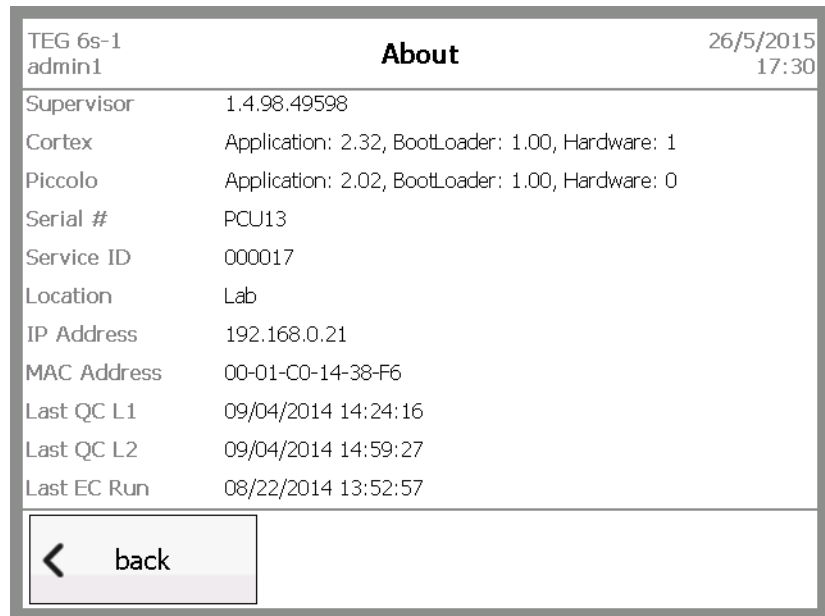


Figure 4-18, About screen

3. Touch **back** to return to the *Settings* screen.

Chapter 5

Operating the TEG[®] Analyzer

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Operation Overview

This chapter explains how to operate the TEG® 6s analyzer and includes instructions for the following:

- Running a patient test
- Stopping a test
- Viewing stored patient data



Caution: Before running tests on the TEG analyzer, you should be familiar with all necessary safety precautions outlined in Chapter 3, "Safety and Precautions".



Note: Before running tests, ensure that the system date and time displayed in the top right corner of the display screen is correct. See "Configure date and time settings" on page 45 for more information.

Disposable assay cartridges

Haemonetics disposable assay cartridges should be kept in their sealed pouches and in the specified storage conditions (2-8 deg C) until just before use. Cartridges can be used straight from the refrigerator; they do not need to come to room temperature before using.

Before opening the cartridge pouch, verify that you have the proper cartridge for the assay you wish to run. Tear the pouch at the provided notch to remove the cartridge and then place the cartridge in the analyzer when prompted.

Inserting the cartridge triggers a barcode scan and pretest of the cartridge. At the successful completion of the pretest, the analyzer prompts you to verify that the assay being run is what is intended.

In the event that the cartridge pretest fails, the analyzer prompts you to insert a new cartridge or contact service personnel if the problem persists.



Caution: DO NOT remove a cartridge until prompted to do so, either after normal completion of the test or as a result of choosing to stop the test.

Blood samples

Blood should be drawn by a trained phlebotomist following proper techniques and standards. Depending on the test, either citrated or heparinized blood should be drawn into a matching Vacutainer® tube.



Notes:

- All blood tubes must be completely filled by vacuum. A short draw is not an acceptable sample.
- Never check for clots in a TEG blood sample by using a wooden stick. Always check for clots visually.
- Citrated or heparinized samples should be tested **no earlier than fifteen minutes** after being drawn and **no later than 2 hours** post draw.

Running a Patient Test

Quick guide for running a patient test

1. From the *Home* screen, touch **new test**.
2. On the *Select Patient* screen, select the patient ID you wish to use. If the patient is not listed, add a new patient by touching **+** and entering a patient ID on the *Add Patient* screen. Then touch **next**.
3. Insert the cartridge into the slot, as indicated on the screen, with the bar code on the left side.
4. Verify that the cartridge type is correct, and then touch **next**.
5. On the *Test Information* screen, enter information for the test, and then touch **next**.
6. Add blood to the cartridge sample port, filling up to or above the line marked on the cartridge, and then touch **next**.
7. View the test results on the results and/or tracing screens.
8. When prompted to remove the cartridge, dispose of it properly.
9. Touch **done** to return to the main menu.

Detailed guide for running a patient test

1. From the *Home* screen, touch **new test**.

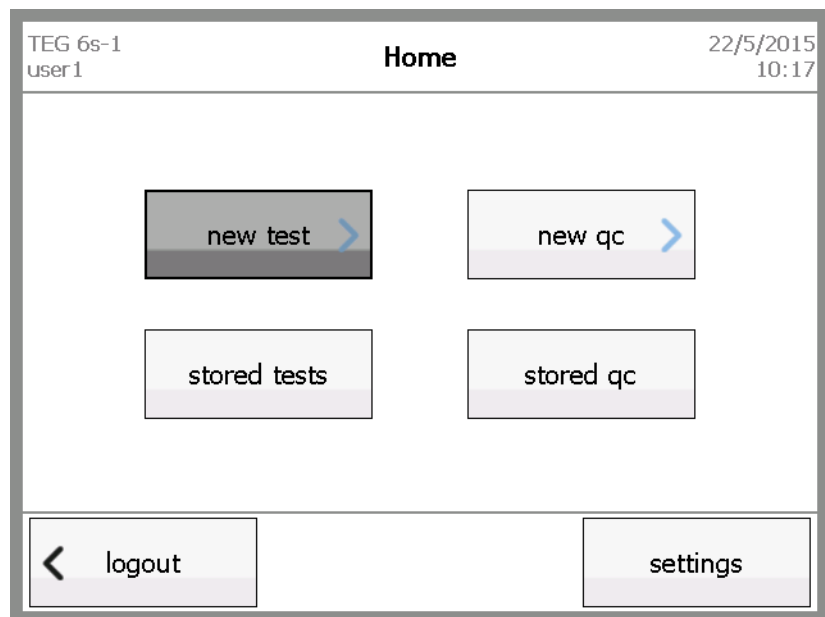


Figure 5-1, Home screen - touch **new test**

2. On the *Select Patient* screen, select the desired patient ID.



Tip: Use the up and down arrows on the right side of the screen to scroll through the list of patient IDs.

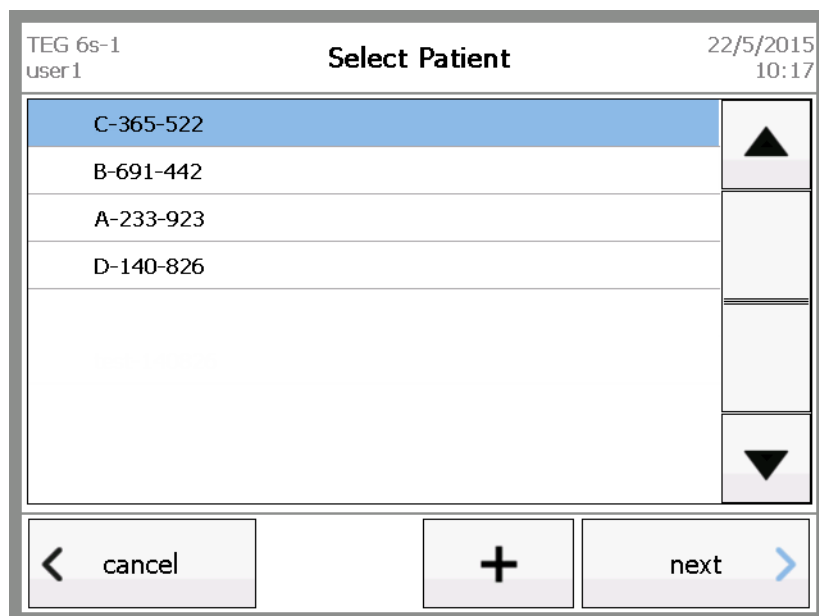


Figure 5-2, Select Patient screen

3. (Optional) If the patient is not listed, add a new patient ID by doing the following:
 - a. Touch **+**.
 - b. On the *Add Patient* screen, enter a new patient ID (maximum of 20 characters) for the analyzer, and then touch **ok**.

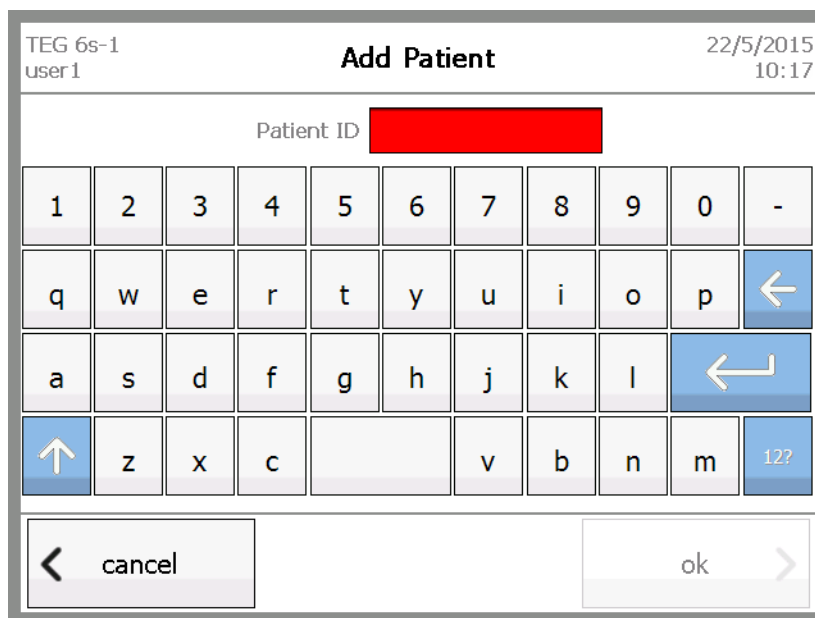


Figure 5-3, Add Patient screen

- c. On the *Select Patient* screen, select the new patient ID.
4. On the *Select Patient* screen, touch **next**.

5. If the analyzer is linked to TEG Manager and a Library Information System (LIS), the *Confirm Patient Data* screen displays the name, date of birth, and gender of the patient.

Confirm Patient Data	
Name	Patient B
Date of Birth	22-Oct-1980
Gender	Male
< reject	confirm >

Figure 5-4, Confirm Patient Data screen

Do one of the following:

- Touch **confirm** if the patient information is correct.
- Touch **reject** if the patient information is incorrect.

In the confirmation message that appears, touch **yes** if you wish to continue the test with rejected patient data, or touch **no** to return to the *Select Patient* screen.

6. Remove the desired patient test cartridge from its sealed pouch.
7. Insert the cartridge into the slot, as indicated on the *Preparing Test – Insert cartridge* screen, with the bar code on the left side.



Note: Only a Haemonetics assay cartridge can be inserted into the cartridge slot. Check the label to be sure you are using the intended assay.

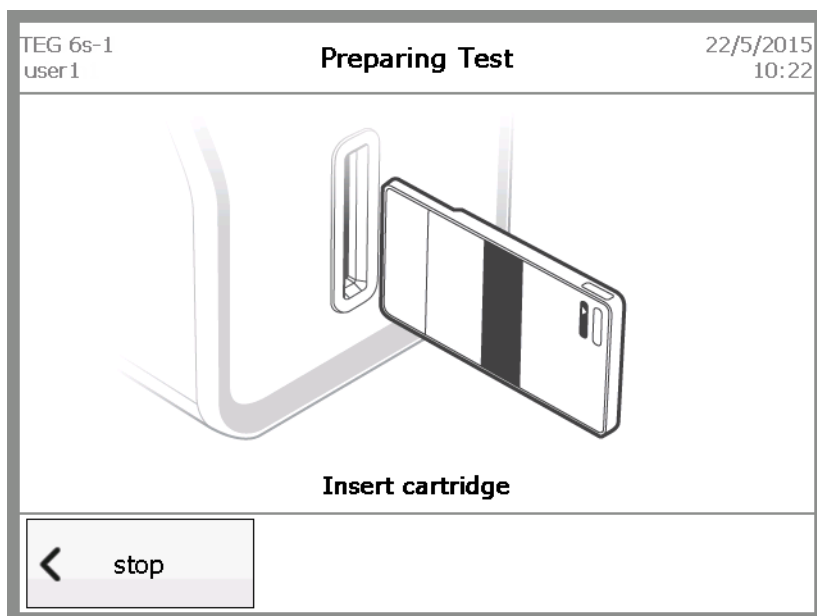


Figure 5-5, Preparing Test - Insert cartridge screen



Caution: DO NOT remove the cartridge until prompted to do so, either after normal completion of the test or as a result of choosing to stop the test.

8. On the *Preparing Test – Verify cartridge* screen, review the information to ensure that the cartridge type displayed on the screen is correct, and then touch **next**.



Tip: The color of the test tube indicates the type of blood sample to be used for the test.

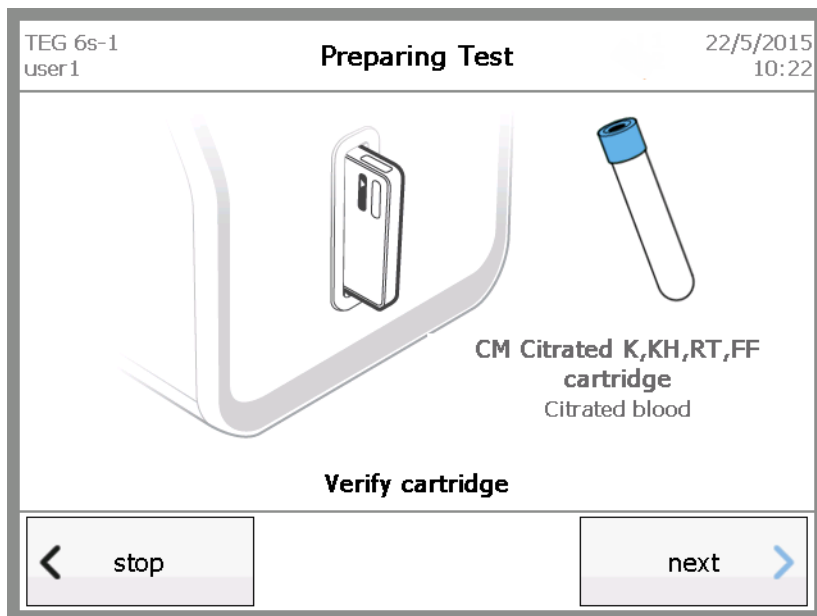


Figure 5-6, Preparing Test - Verify cartridge screen

9. On the *Test Information* screen, enter information for the test (for example, a treatment phase), if desired, and then touch **next**.

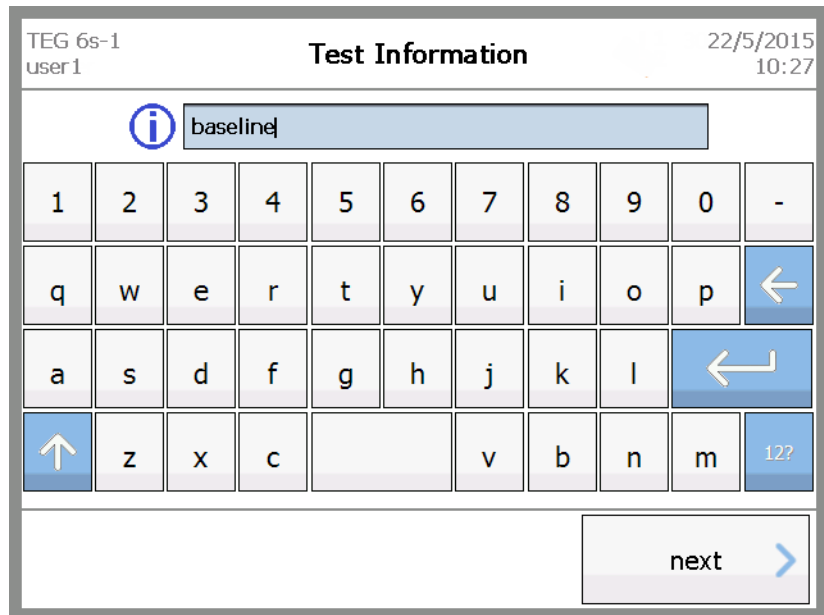


Figure 5-7, Test Information screen

The *Preparing Test – Load sample* screen displays.

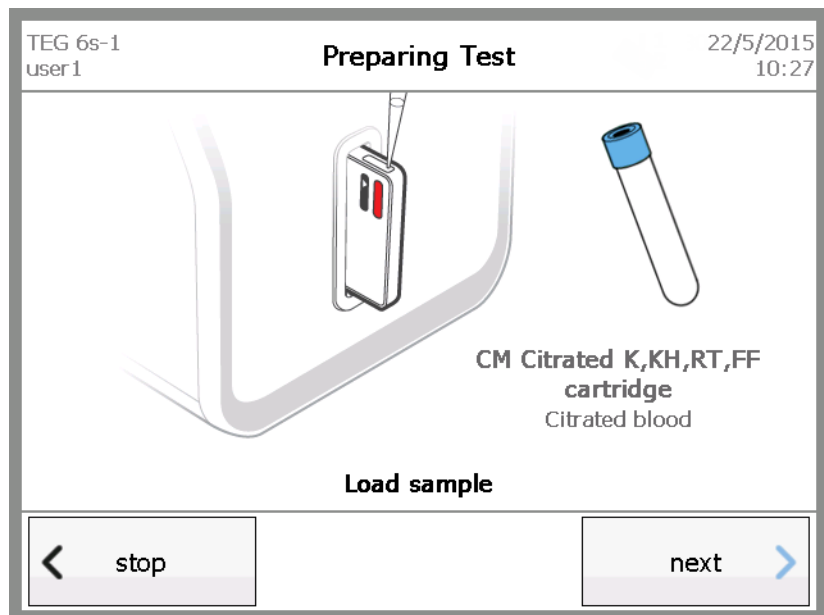


Figure 5-8, Preparing Test - Load sample screen

10. Using a pipette or syringe, load blood into the cartridge sample port, filling up to or above the line marked on the side of the cartridge.



Note: Precise measurement is not necessary; any excess blood is moved to a sealed waste area within the cartridge during the test.

11. Touch **next**.

The TEG analyzer starts the test, and the results screen displays. Figure 5-9 shows an in-progress assay after 16 minutes has elapsed.

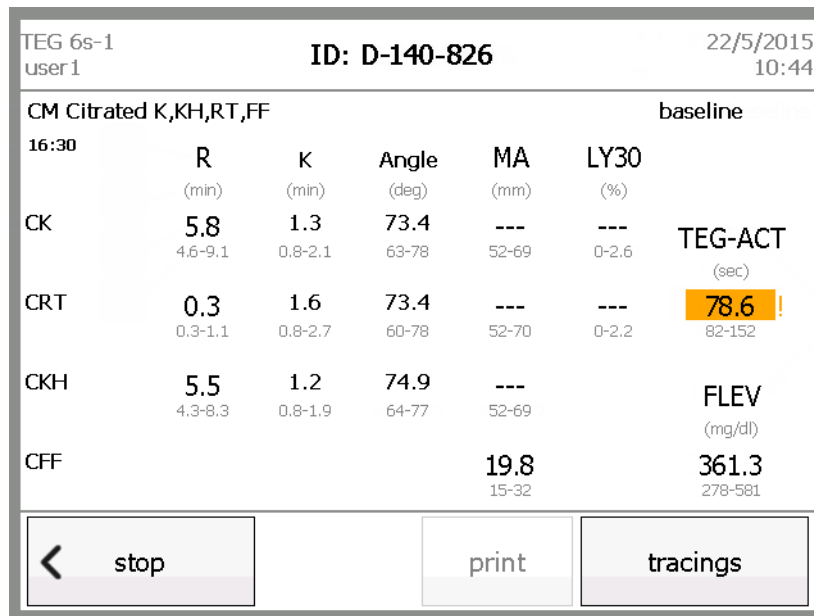


Figure 5-9, Test results (in progress)

12. Touch **tracings** to view a graphic representation of the results. To cycle through superimposed, offset, and single-tracing views, touch **next tracing** until the desired view is displayed. (For more information, see "Tracing screens" on page 43).

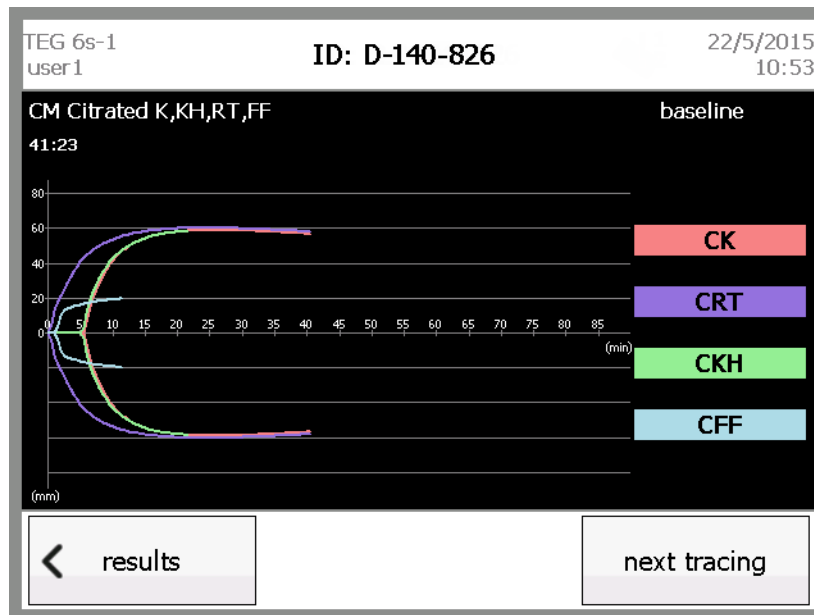


Figure 5-10, Test results (superimposed tracing)

13. Touch **results** to return to the results screen. When the test is complete, the following changes occur on the results screen:
- The test timer is replaced by the date and time that the test started.
 - The **stop** button is replaced by a **done** button.
 - The **print** button is enabled.

TEG 6s-1 user1		ID: D-140-826				22/5/2015 10:53	
CM Citrated K,KH,RT,FF						baseline	
27/8/2014 06:54	R	K	Angle	MA	LY30		
	(min)	(min)	(deg)	(mm)	(%)		
CK	5.8	1.3	73.4	58.5	2.3	TEG-ACT	
	4.6-9.1	0.8-2.1	63-78	52-69	0-2.6	(sec)	
CRT	0.3	1.6	73.4	59.7	1.5	78.6 !	
	0.3-1.1	0.8-2.7	60-78	52-70	0-2.2	82-152	
CKH	5.5	1.2	74.9	58.5		FLEV	
	4.3-8.3	0.8-1.9	64-77	52-69		(mg/dl)	
CFF				19.8		361.3	
				15-32		278-581	
done			print		tracings		

Figure 5-11, Test results - complete

14. When the analyzer displays the “Remove cartridge” prompt, pull the used cartridge out of the slot and immediately dispose of it in a marked, biohazard waste receptacle.



Note: A flashing light at the cartridge slot also indicates that it is safe to remove a cartridge.

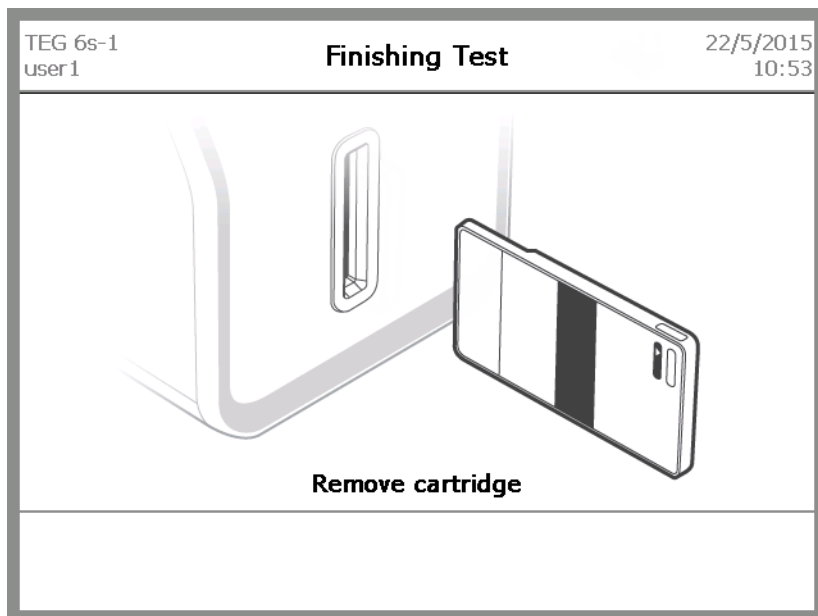


Figure 5-12, Finishing Test - Remove cartridge screen

Stopping a Test

A patient or QC test stops automatically when the requisite parameters for the test have finalized. At times, it can be advantageous to stop a test early; for example, if LY30 is not required by the clinician, you can manually stop the test after MA has finalized.



*Note: You can also cancel a test by touching **stop** from the Preparing Test screens. This may be necessary if you realize that you have inserted the incorrect cartridge.*

To manually stop a test:

1. From the results screen, touch **stop**.

TEG 6s-1		ID: D-140-826				27/5/2015	
user1						11:07	
PM Platelet Mapping					baseline		
29:00	R	K	Angle	MA	LY30	Inhibition	
	(min)	(min)	(deg)	(mm)	(%)	(%)	
HKH	6.6	1.7	68.2	61.8	---	ADP	4.1
	4.2-9.8	1-2.9	57-75	54-70	0-2.4		0-17
ActF				7.6		AA	0
				2-19			0-11
ADP				59.6		Aggregation	
				44-69		ADP	95.9
							83-100
AA				61.9		AA	100
				37-71			89-100
		stop		print		tracings	

Figure 5-13, Touch the **stop** button to stop the test early

The analyzer prompts you to save the collected data.

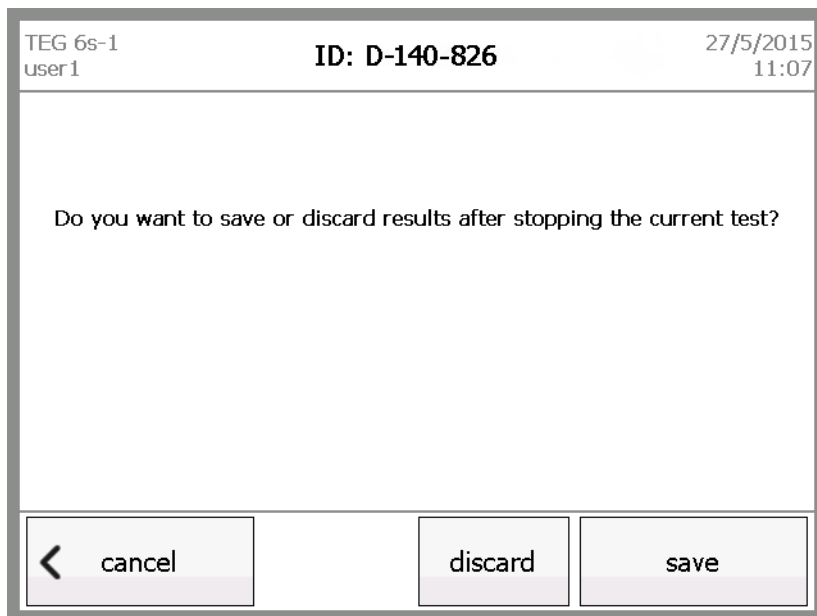


Figure 5-14, Stopped test screen for a patient test

2. Do one of the following:

- Touch **discard** to delete the test and return to the main menu.
- **Touch save** to store the partial test.



Note: If partial results are saved, the test record shows that the run was aborted by the user.

- Touch **cancel** to continue the test.

Viewing Stored Patient Data

Quick guide for viewing stored patient data

1. From the *Home* screen, touch **stored tests**.
2. On the *Stored Tests* screen, select the desired test, and then touch **results**.
3. On the results screen for the selected test, view the results.
4. If desired, touch **tracings** to view a graphic representation of the results. To return to the results page, touch **results**.
5. Touch **back** to return to the *Stored Tests* screen.
6. Touch **home** to return to the *Home* screen.

Detailed guide for viewing stored patient data

1. From the main menu touch **stored tests**.

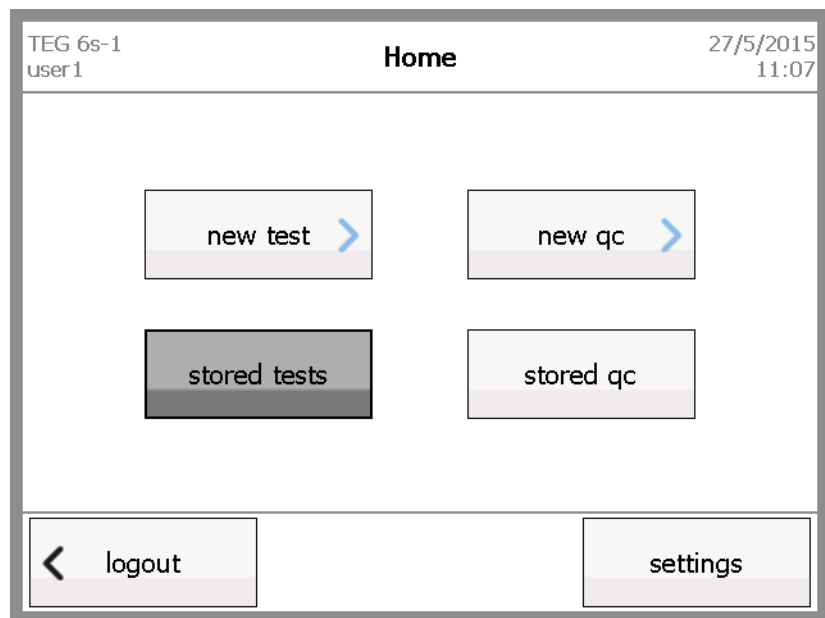


Figure 5-15, Home screen - touch **stored tests**

2. On the *Stored Tests* screen, select the desired test.



Tip: Use the up and down arrows on the right side of the screen to scroll through the list of completed patient tests.

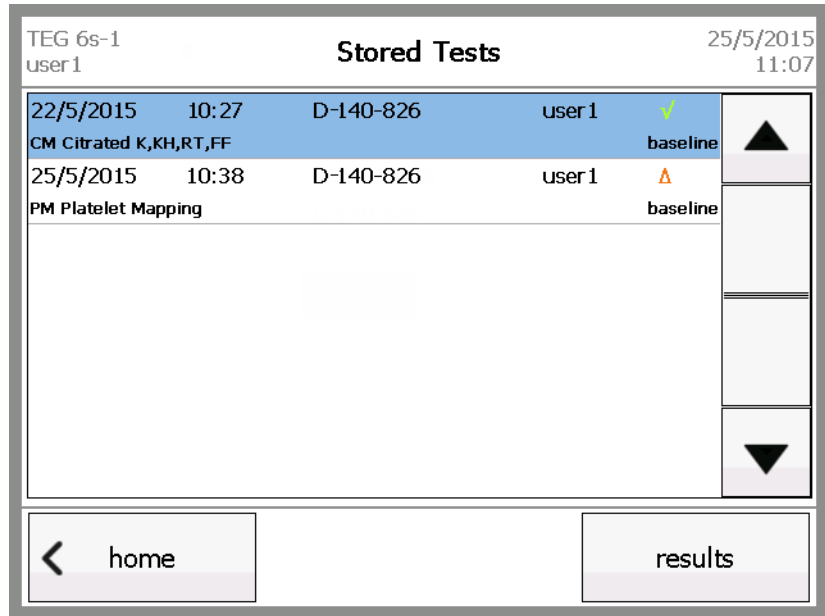


Figure 5-16, Stored Tests screen



Note: The status of each test is shown on the right side of the screen. A green check mark indicates that the test completed (all parameters were finalized), and an orange triangle indicates that the test was stopped early.

3. Touch **results** to view the results screen for the test.

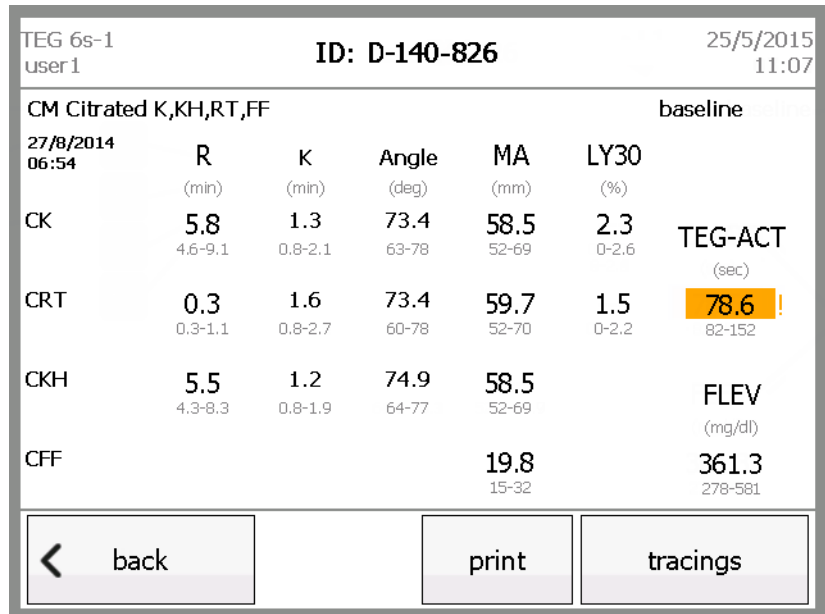


Figure 5-17, Results screen

4. If desired, view the tracings for the test by touching **tracings**. To cycle through superimposed, offset, and single-tracing views, touch **next tracing** until the desired view is displayed. (For more information, see [“Tracing screens” on page 43](#))

Touch **results** to return to the results screen.

5. If desired, touch **print** to print the test results for the patient.



Note: If no printer is attached to the analyzer, a “Failed to print results” error message displays. For more information, see [“Printer specification” on page 89](#).

6. Touch **back** to return to the *Stored Tests* screen.
7. Touch **home** to return to the *Home* screen.

Chapter 6

Quality Control

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Performing Quality Control Tests

This chapter explains how to run quality controls (QC) on the TEG® 6s analyzer and includes instructions for the following:

- Running a QC test
- Viewing stored QC data


QC consists of a vial with lyophilized biological material and a matching disposable cartridge for performing a test. When a QC cartridge is inserted into the TEG analyzer, it triggers a script that verifies the performance and accuracy of the analyzer.

Quality control output


Haemonetics provides two QC preparations, Level 1 (L1) and Level 2 (L2), to use in your quality control protocol. Refer to the product inserts for details about what the controls contain and instructions on preparation, use, and expected results. L1 has been formulated to simulate a higher MA, while L2 simulates a lower MA.

Quality control schedule

The TEG analyzer can be configured to require successful quality control testing at a particular time interval. This interval is determined by hospital policy and configured by the System Administrator.

When the end of the specified interval is approaching, the analyzer displays a warning message indicating that QC testing is due soon. When the interval is exceeded, a “QC overdue”  icon displays at the top of the screen.

Depending on how the analyzer is configured, one of the following occurs when the QC interval is expired:

- The analyzer prevents you from running patient tests until the L1 and L2 QC tests are successfully run.
- The analyzer allows you to run tests, but any test that is run after the QC interval has expired is flagged as being out of QC. A “Test run with QC overdue”  icon is displayed on the results screen for the test.

Quick guide for running a QC test

1. From the *Home* screen, touch **new qc**.
2. Insert the cartridge into the slot, as indicated on the screen, with the bar code on the left side.
3. Verify that the cartridge type is correct, and then touch **next**.
4. On the *Test Information* screen, enter information for the test (if desired), and then touch **next**.

5. Prepare the QC sample according to the manufacturer's instructions.
6. Pipette the QC sample into the cartridge sample port, filling up to or above the line marked on the cartridge, and then touch **next**.
7. View the test results on the results and/or tracing screens.
8. When prompted to remove the cartridge, dispose of it properly.
9. Touch **done** to return to the main menu.

Detailed guide for running a QC test

1. From the *Home* screen, touch **new qc**.

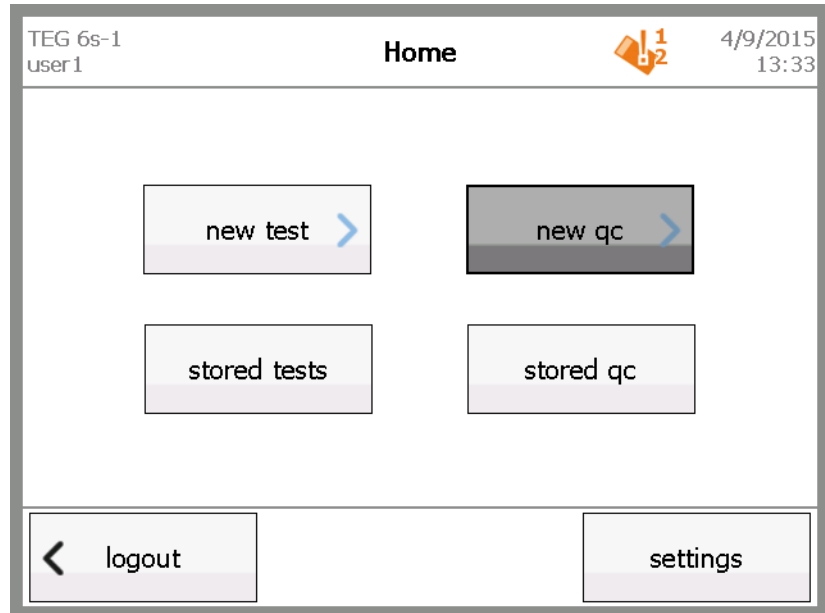


Figure 6-1, Home screen – touch **new qc**

2. Remove the desired QC cartridge from its sealed pouch.
3. Insert the cartridge into the slot, as indicated on the *Preparing Test – Insert cartridge* screen, with the bar code on the left side.



Note: Only a Haemonetics QC cartridge can be inserted into the cartridge slot. Check the label to be sure you are using the intended QC assay.

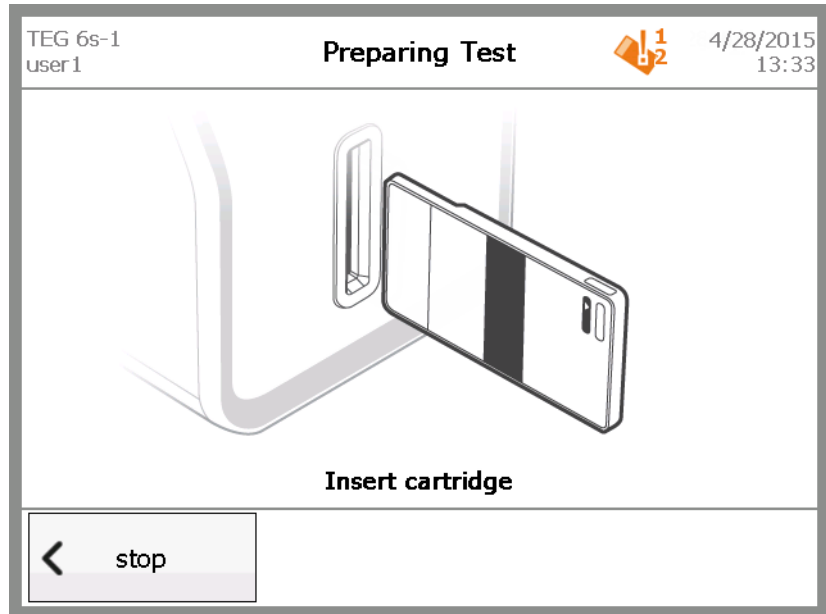


Figure 6-2, Insert cartridge screen



Caution: DO NOT remove the cartridge until prompted to do so, either after normal completion of the test or as a result of choosing to stop the test.

4. On the *Verify cartridge* screen, review the information to ensure that the cartridge type displayed on the screen is correct, and then touch **next**.

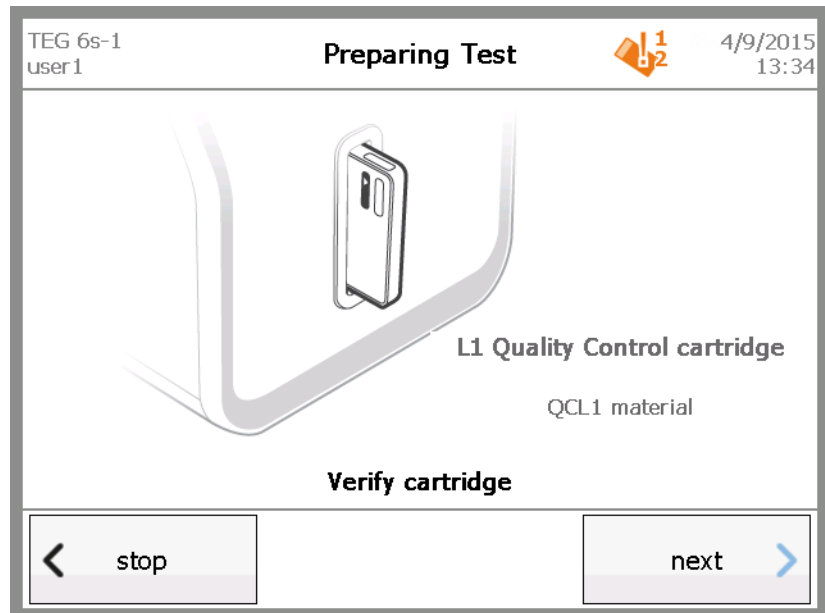


Figure 6-3, Verify cartridge screen

5. On the *Test Information* screen, enter information for the test, if desired, and then touch **next**.

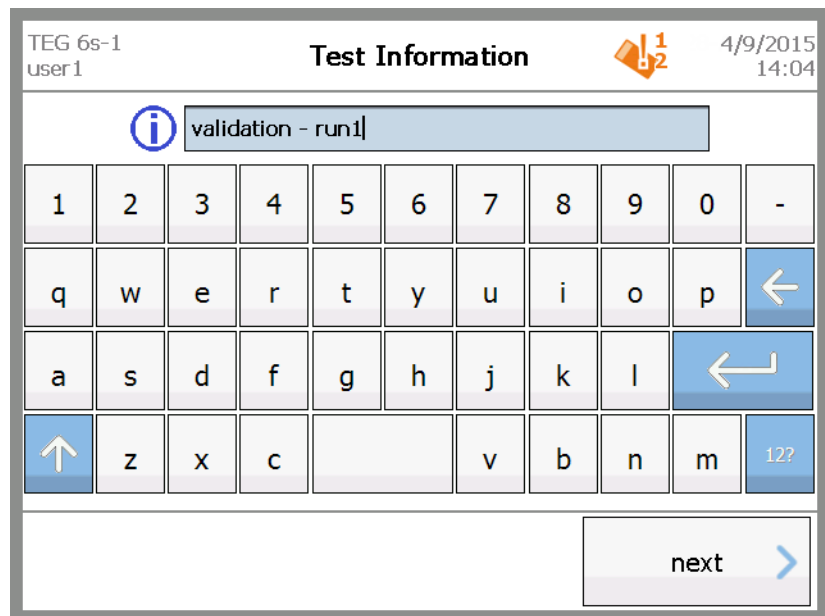


Figure 6-4, Test information screen

The *Preparing Test – Load sample* screen displays.

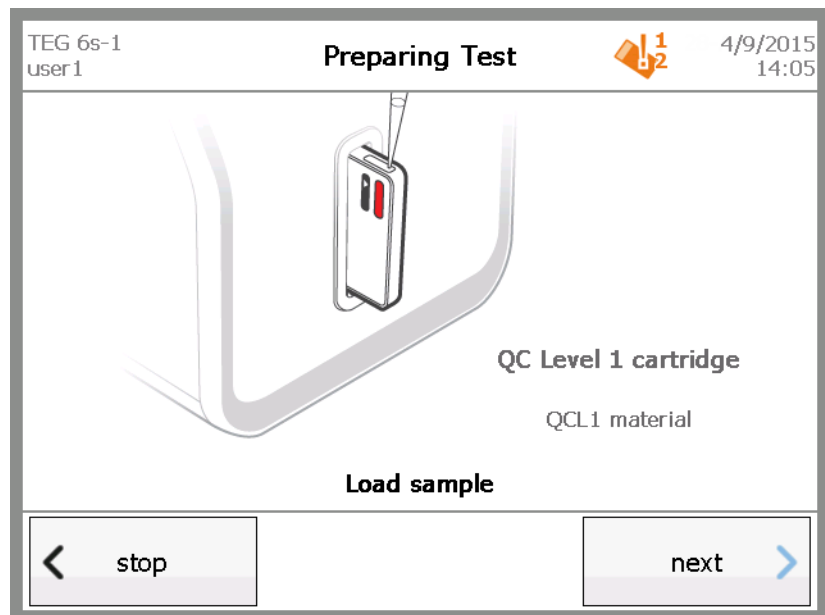


Figure 6-5, *Preparing Test – Load sample* screen

6. Prepare the QC material according to the instructions in the package insert.



Note: Each QC vial, once reconstituted, contains 1ml of QC material, which is sufficient for two QC assays.

7. Pipette the prepared QC sample into the cartridge sample port, filling up to or above the line marked on the cartridge.

8. Touch **next**.

The TEG analyzer starts the QC test, and the results screen displays. Figure 6-6 shows an in-progress assay after 14 minutes has elapsed.

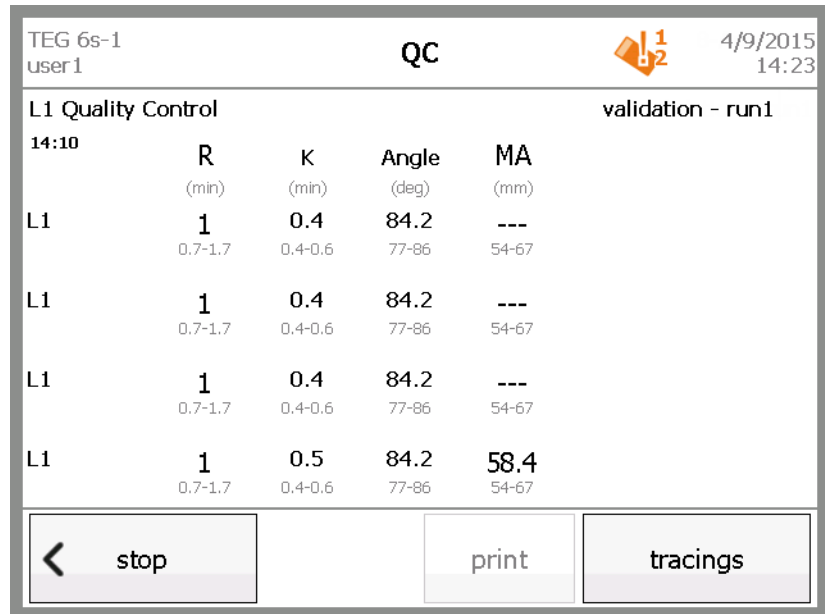


Figure 6-6, QC test results (in progress)

9. Touch **tracings** to view a graphic representation of the results. To cycle through superimposed, offset, and single-tracing views, touch **next tracing** until the desired view is displayed. (For more information, see “Tracing screens” on page 43).

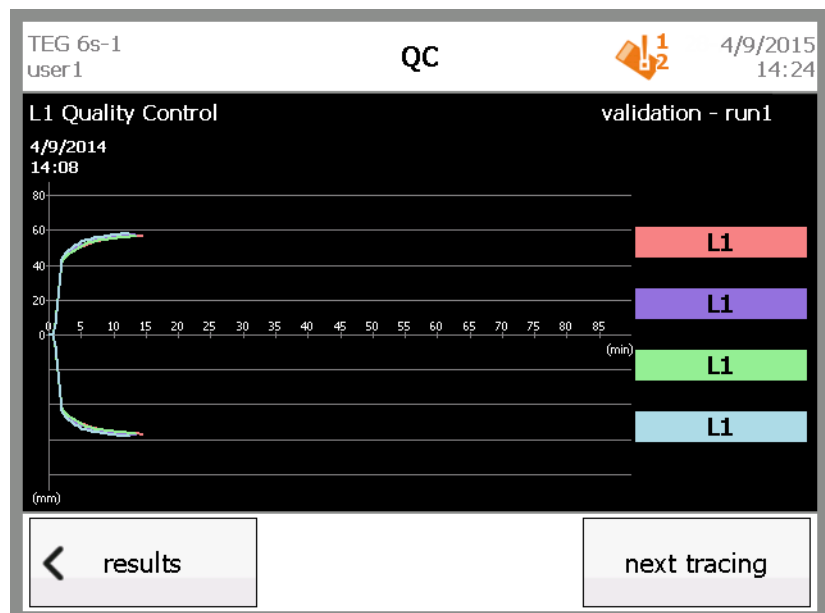


Figure 6-7, Test results (superimposed tracing)

10. Touch **results** to return to the results screen. When the test is complete, the following changes occur on the results screen:
- The test timer is replaced by the system date and time.
 - The status of each channel is shown on the right side of the screen. A green check mark ✓ indicates that QC passed for the channel, and a red X indicates that QC failed for the channel.
 - If all four channels passed, the "QC overdue" icon at the top of the screen no longer shows the QC level that passed.
 - The **stop** button is replaced by a **done** button.
 - The **print** button is enabled.



TEG 6s-1 user1		QC				4/9/2015 14:25
L1 Quality Control					validation - run1	
4/9/2014 14:08	R	K	Angle	MA	QC : ✓	
	(min)	(min)	(deg)	(mm)		
L1	1	0.4	84.2	57.1	✓	
	0.7-1.7	0.4-0.6	77-86	54-67		
L1	1	0.4	84.2	57.5	✓	
	0.7-1.7	0.4-0.6	77-86	54-67		
L1	1	0.4	84.2	56.8	✓	
	0.7-1.7	0.4-0.6	77-86	54-67		
L1	1	0.5	84.2	58.4	✓	
	0.7-1.7	0.4-0.6	77-86	54-67		
 done		print		tracings		

Figure 6-8, QC test results (complete)

11. When the analyzer displays the "Remove cartridge" prompt, pull the used cartridge out of the slot and immediately dispose of it in a marked, biohazard waste receptacle.



Note: A flashing light at the cartridge slot also indicates that it is safe to remove a cartridge.

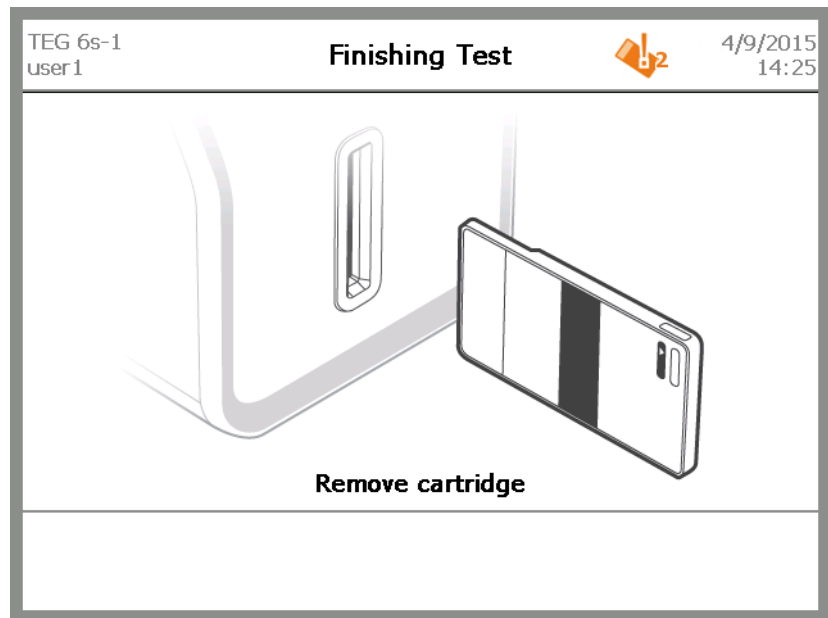


Figure 6-9, Finishing Test – Remove cartridge screen

Viewing Stored QC Data

Quick guide for viewing stored QC data

1. From the *Home* screen, touch **stored qc**.
2. On the *Stored QC* screen, select the desired test, and then touch **results**.
3. On the QC screen for the selected test, view the results.
4. If desired, touch **tracings** to view a graphic representation of the results. To return to the results page, touch **results**.
5. Touch **home** to return to the *Home* screen.

Detailed guide for viewing stored QC data

1. From the *Home* screen touch **stored qc**.

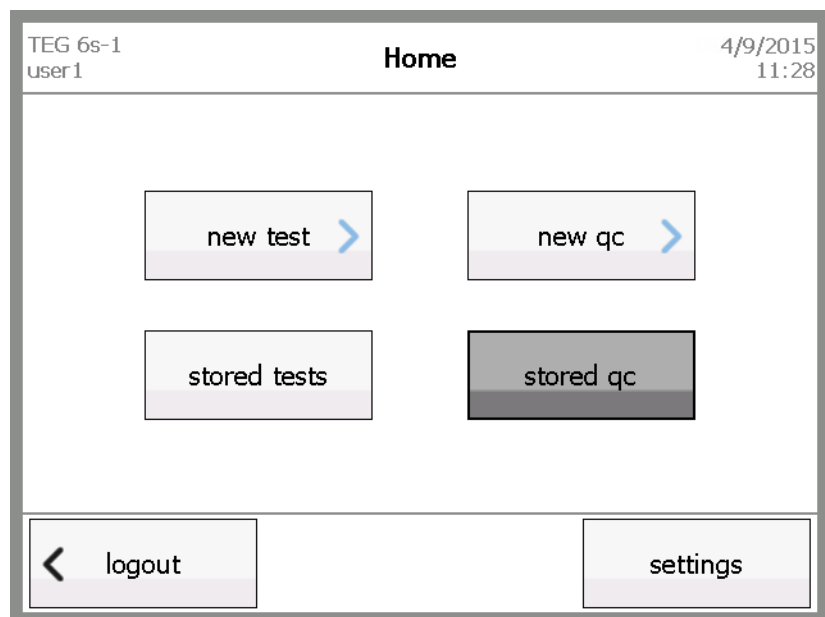


Figure 6-10, Home screen - touch **stored qc**

2. On the *Stored QC* screen, select the desired test, and then touch **results**.



Tip: Use the up and down arrows on the right side of the screen to scroll through the list of completed QC tests.

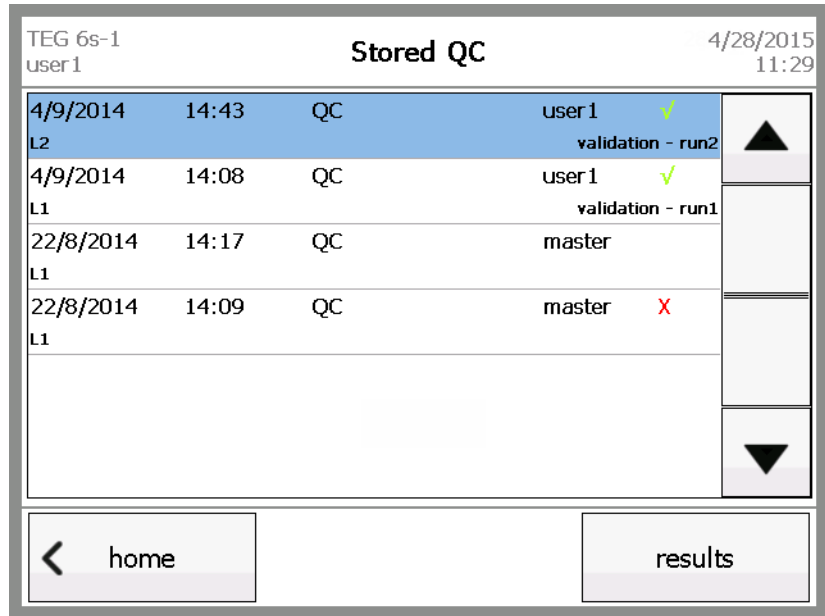


Figure 6-11, Stored QC screen

- On the QC screen, view the test results.

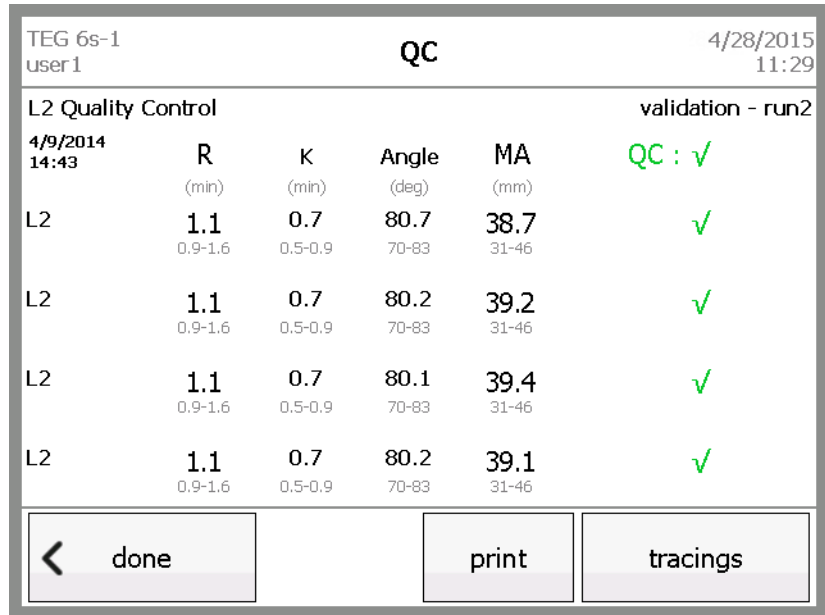


Figure 6-12, Viewing QC test results

- If desired, view the tracings for the test by touching **tracings**. To cycle through superimposed, offset, and single-tracing views, touch **next tracing** until the desired view is displayed.
Touch **results** to return to the results screen.
- If desired, touch **print** to print the QC results.



Note: If no printer is attached to the analyzer, a “Failed to print results” error message displays. For more information, see [“Printer specification” on page 89](#).

6. Touch **back** to return to the *Stored QC* screen.
7. Touch **home** to return to the *Home* screen.

Chapter 7

Troubleshooting and Maintenance

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Errors and Alerts

The following section describes common error, warning, and critical alert messages that may display on the TEG® 6s analyzer.



For all error and alert messages, the analyzer emits an audible tone at the same time as the message is displayed on the touchscreen.



Note: If any problem persists after performing the recommended correction, contact the local Haemonetics representative to arrange for repairs or return (see “Customer Service” on page 12). Be prepared to describe the problem and report the error code number that accompanied the error message.

Error messages

When an error occurs, the TEG analyzer displays a description of the error and instructions for correcting the issue. An error causes the test to stop and may require you to replace the cartridge or to turn the power off and back on in an attempt to clear the error. Follow the instructions on the error message to prevent further errors.



Note: If an error occurs during data collection, the data is NOT saved.

Figure 7-1 shows an example of an error message screen.

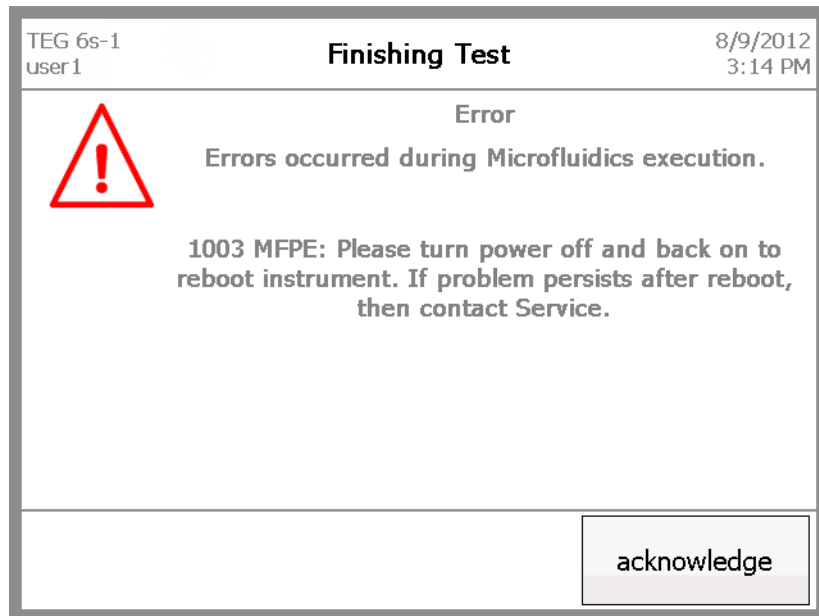


Figure 7-1, Error screen



Caution: *If an error is triggered by a faulty cartridge, remove the cartridge and rerun the test with a new cartridge. DO NOT attempt to repair or reuse the old, faulty cartridge.*

Warning messages

A warning occurs when the device encounters an unknown situation and is usually indicative of equipment or cartridge malfunction rather than user error. A warning does not require you to take a specific action; instead, it alerts you to an occurring event which you acknowledge by touching the **acknowledge** button. The test continues to run.

If a warning message appears to be indicative of a larger problem, it is advisable to contact the local Haemonetics representative to report the problem.



Note: If a warning occurs during data collection, no data is lost.

Figure 7-2 shows an example of a warning message screen.

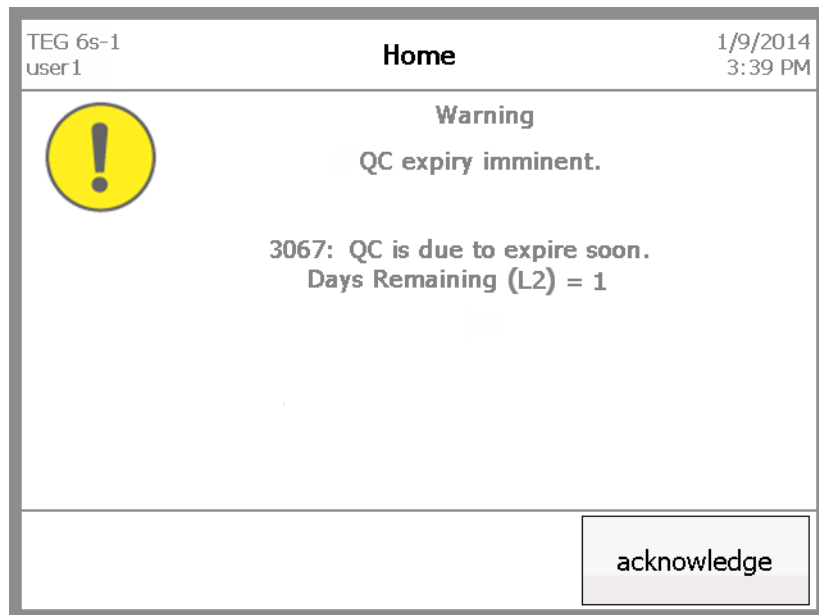


Figure 7-2, Warning screen

Critical alert messages

A critical alert message occurs when the system encounters an unrecoverable error. In this case, the analyzer must be turned off and back on to reboot the system. If this does not clear the error, contact the local Haemonetics representative to report the problem.



Note: If a critical alert message occurs during data collection, the data is NOT saved.

Figure 7-3 shows an example of a critical error message screen.

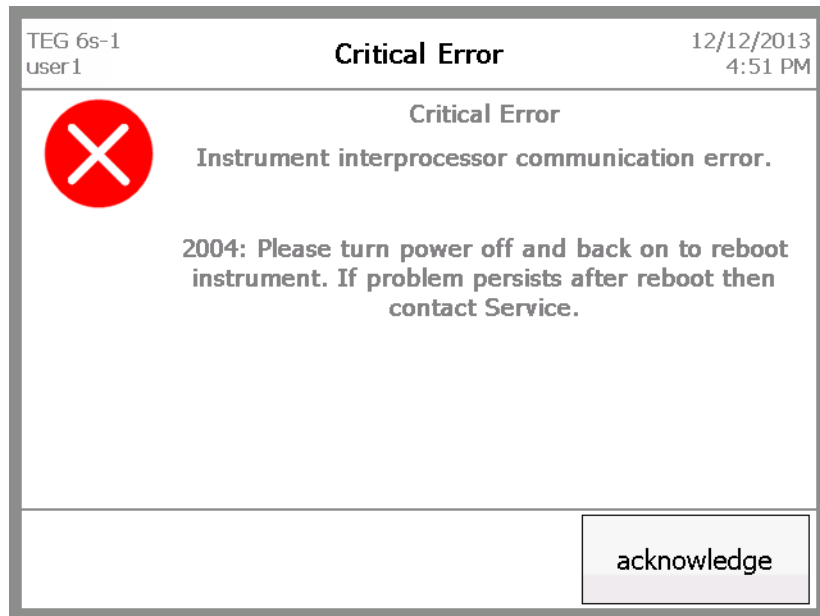


Figure 7-3, Critical error screen



Error message table


The following table provides some examples of errors and alerts that you may encounter and includes the error code, display message, probable cause, and recommended solution. For error codes that are displayed on the analyzer but are not included in the table, please contact the local Haemonetics representative for assistance.



Error Code	LCD Display Message	Probable Cause	Recommended Action
1000	The instrument has unexpectedly been reset.	The analyzer was unexpectedly reset while idle.	Turn the power off and then back on to reboot the analyzer. If the problem persists, contact the local Haemonetics representative.
1005	Power-On-Self-Test optics error.	During POST, one or more photodetectors are reading abnormally high or low, or it was not possible to calibrate the excitation LED(s) as desired.	Turn the power off and then back on to reboot the analyzer. If the problem persists, contact the local Haemonetics representative.
1010	Power-On-Self-Test vacuum leak error.	A vacuum leak was detected during POST.	Turn the power off and then back on to reboot the analyzer. If the problem persists, contact the local Haemonetics representative.

Error Code	LCD Display Message	Probable Cause	Recommended Action
1016	Bubble detected in channel.	Bubbles have been detected in one or more channels.	Remove the cartridge and rerun the test using a new cartridge. Verify that the quantity of blood sample is sufficient for the test. If the problem persists, contact the local Haemonetics representative.
1030	Pressure leak in instrument	There was a pressure leak in the analyzer.	Contact the local Haemonetics representative.
1031	Pressure leak in cartridge	There was a pressure leak in the cartridge.	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
1032	Vacuum leak in instrument	There was a vacuum leak in the analyzer.	Contact the local Haemonetics representative.
1033	Vacuum leak in cartridge	There was a vacuum leak in the cartridge.	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
1034	Regulated vacuum error in cartridge	The regulated vacuum was out of range when the cartridge was clamped.	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
1037	Regulated pressure error in instrument	The regulated vacuum was out of range when the cartridge was <i>not</i> clamped.	Contact the local Haemonetics representative.
2001	Front panel LED failure	The front panel LED failed.	The analyzer will continue to operate correctly. Report the failure to the local Haemonetics representative.

Error Code	LCD Display Message	Probable Cause	Recommended Action
2003	The instrument has unexpectedly been reset during a Test	The analyzer was unexpectedly reset while a test was running.	Turn the power off and then back on to reboot the system. Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
3000	Sample temperature out of range for one or more channels	At least one channel has a heater temperature which is more than the maximum temperature deviation from the set point for that channel.	Remove the cartridge and contact the local Haemonetics representative.
3005	DC offset out of range for one or more channels.	Optics error during data collection	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
3008	Sample initial fill level out of range for one or more channels.	Too little sample was delivered to the cartridge rings, may indicate issues with optics, pressure or cartridge	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
3009	Sample has evaporated in one or more channels.	Sample evaporation during a test	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
3011	Data processing error in one or more channels, indicated by sudden optical sensor output change.	Unexpected change from the optical sensor.	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
3013	Data processing error in one or more channels, indicated by progressive optical sensor output change.	Unexpected change from the optical sensor.	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
3017	QC has expired and must be run again to enable patient tests	QC interval has been exceeded.	Run a QC test using a QC cartridge.

Error Code	LCD Display Message	Probable Cause	Recommended Action
3019	Firmware update failed	There is a mismatch between the existing firmware and the updated firmware, which causes the automatic update to fail.	<p>Turn the power off and then back on to reboot the system. If the problem persists, update the firmware again or reset the system to the previous firmware revision.</p> <p> <i>Note: This action requires administrator access; if no administrator is available or if the problem persists, contact the local Haemonetics representative.</i></p>
3027	Power-On-Self Test Fault - Diskspace is critically low	The Power-On Self Test (POST) detected that the available disk space is below the minimum threshold.	<p>Delete unneeded test results from the analyzer, and then turn the power off and back on to reboot the system.</p> <p> <i>Note: This action requires administrator access; if no administrator is available or if the problem persists, contact the local Haemonetics representative.</i></p>

Error Code	LCD Display Message	Probable Cause	Recommended Action
3032	Instrument program error	A firmware file cannot be located by the system.	Update the system firmware or reset the system to the previous firmware revision.  <i>Note: This action requires administrator access; if no administrator is available or if the problem persists, contact the local Haemonetics representative.</i>
3042	Initial Frequency Error	Starting frequency outside of allowed limits.	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
3054	Error reading barcode.	Barcode cannot be read by analyzer.	Remove the cartridge and rerun the test using a new cartridge. If the problem persists, contact the local Haemonetics representative.
3056	Attempting to run a Patient test using a QC test cartridge	The cartridge test type is QC but you have attempted to run a patient test.	Remove the QC cartridge and insert a patient test cartridge.
3060	QC cartridge expiration date has passed	The system has detected that the QC cartridge expiration date has passed.	Remove the expired QC cartridge.

Error Code	LCD Display Message	Probable Cause	Recommended Action
3061	Cartridge Store Table update required. See Administrator for assistance.	The QC cartridge may be expired. An update to the Cartridge Store Table is required to determine the expiration date.	<p>Contact the System Administrator for assistance in downloading a new Cartridge Store Table.</p> <p> <i>Note: This action requires administrator access; if no administrator is available, contact the local Haemonetics representative. For more information, see “Cartridge Library” on page 22.</i></p>
3063	Cartridge Store Table update required. See Administrator for assistance.	The Patient test cartridge may be expired. An update to the Cartridge Store Table is required to determine the expiration date.	<p>Contact the System Administrator for assistance in downloading a new Cartridge Store Table.</p> <p> <i>Note: This action requires administrator access; if no administrator is available, contact the local Haemonetics representative. For more information, see “Cartridge Library” on page 22.</i></p>
3069	Sample delivery timeout.	Delivery of sample to test area did not complete in expected time.	<p>Remove the cartridge and rerun the test using a new cartridge. Verify that volume of blood sample is sufficient for the test. Fill up to or above the line marked on the side of the cartridge. If the problem persists, contact the local Haemonetics representative.</p>

Error Code	LCD Display Message	Probable Cause	Recommended Action
3071	Over 90% of stored patient records have not been backed-up or printed.	The analyzer (in stand-alone mode) is approaching the maximum storage capacity (300) for patient tests and 90% of the tests have not been printed or backed up.	Print the tests or contact the System Administrator to perform a backup of the analyzer.

Cleaning and Disinfecting the Analyzer

The surfaces of the TEG analyzer must be wiped down and disinfected weekly, or more frequently, as needed. Use laboratory medical disinfecting procedures to prevent contamination of the analyzer and limit potential exposure of bloodborne pathogens to operating personnel.

Products containing a 70% isopropyl alcohol solution are recommended, and commonly-used germicidal disposable wipes (PDI Super Sani-Cloth® or equivalent) are effective and will not cause damage to the TEG analyzer when used according to manufacturer's instructions.

The TEG analyzer must also be cleaned and disinfected prior to return shipment if servicing is necessary. For further information, see "[Product return guidelines](#)" on page 12.

All materials used for disinfecting should be disposed of in the proper biohazard waste receptacles.

**Caution:**

- Turn off the analyzer and unplug it from the wall before cleaning.
- Do not steam-sterilize or autoclave the analyzer or any cartridge.
- Do not immerse the analyzer or cartridge in any solution.
- Do not clean the analyzer or cartridge with acetone or any other plastic solvent or abrasive cleaner.



Note: If there is any doubt about the compatibility of decontamination or cleaning agents with parts of the device or with material contained within it, the Administrator or Laboratory Supervisor may consult with Haemonetics or an authorized distributor regarding such use.

Materials needed

- Disposable gloves
- 70-95% isopropyl alcohol plus 2" x 2" gauze pads OR germicidal disposable wipes
- Warm running water

Clean the analyzer

To clean and disinfect the surfaces of the analyzer:

1. Turn off the analyzer and unplug it from the wall.
2. Put on disposable gloves.
3. Using gauze pads soaked in isopropyl alcohol or germicidal disposable wipes, thoroughly clean all external surfaces of the TEG analyzer, including the touch screen.



Caution: Avoid getting liquid into the cartridge slot at the front of the analyzer or into connectors on the rear panel.

Clean the filter

The TEG analyzer has a filter assembly mounted at the rear of the unit to filter air as it is drawn into the unit by the fan. This filter should be washed periodically, depending on frequency and conditions of use.

To clean the filter:

1. Grasp the edges of the filter cover and pull to remove it.
2. Remove the filter from the cover.
3. Rinse the filter under warm running water until it is clean. Do not use soap or any cleaning solution.
4. Squeeze out any excess water, place on a clean cloth, and allow to dry completely.
5. Ensure the filter is 100% dry, and then reinsert the filter into the filter cover.
6. Press the filter cover back onto the analyzer.
7. Record the date of maintenance.

Chapter 8

Specifications and Performance Characteristics

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Specifications

The following tables describe the physical, environmental, and electrical specifications for operating the TEG[®] 6s analyzer.

Physical specifications

The physical specifications of the TEG analyzer are as follows:

Characteristic	Value
Dimensions	Width: 175mm (6.9 in)
	Length: 257mm (10.1 in)
	Height: 270mm (10.6 in)
Weight	4.2 kg (9.4 lbs)
Display	Backlit color LCD, 640x480 resolution, integrated 4-wire touch screen

Environmental specifications

The environmental specifications for the operation and storage of the TEG analyzer are as follows:

Condition	Value
Operating temperature	10°C to 32°C (50°F to 89.6°F)
Operating pressure	0 to 2000 m (0 to 6,560 ft) above sea level
Operating humidity	20% to 80% RH (non-condensing)
Shipping/storage temperature	-20°C to +50°C (-4°F to 122°F)
Shipping/storage humidity	20% to 80% RH (non-condensing)

Electrical specifications

The electrical specifications for operating the TEG analyzer are as follows:

Characteristic	Value
Voltage Rating	100V-240V AC
Power Supply Output Voltage	12 volts DC
Output Power / Current Rating	5 A, 60 W (max)

Characteristic	Value
Supply Frequency	50/60 Hz
Replaceable Fuse – 5 Amp	Manufacturer: SIBA, P/N: GZ179021-5A, 5mm x 20mm, Quick-Action Ceramic, UL Recognized E167295

Printer specification

Haemonetics recommends the Epson TM-T2011 USB thermal receipt printer (118034-00) for use with the TEG analyzer.

Performance Characteristics

FCC Compliance

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case users will be required to correct the interference at their own expense.



Caution: Any changes or modifications not expressly approved by Haemonetics could void the user's authority to operate this equipment.

Warranty

Haemonetics warrants its manufactured products (excluding disposable or consumable supplies) to be free from defects in materials or workmanship for one year from the original date of purchase subject to these terms and conditions. Returns will not be accepted without authorization from a Haemonetics Representative. Products must show no evidence of improper handling or operation, including unauthorized repairs.

At its discretion, Haemonetics may repair or replace defective products covered by this warranty. Even if Haemonetics cannot repair or replace, its entire liability shall in no event exceed the purchase price. Haemonetics expressly disclaims all other warranties, whether express, implied, or statutory, including the warranty of merchantability and fitness of use. In no event will Haemonetics be liable for consequential, incidental, or special damages arising out of the use of its products.