For TEG® Analytical Software (TAS) Version 4.3 users, please refer to the Addendum section of the User Manual for detailed instructions for using the new software features.
Technical Support:

Contact your local service representative, or the main office at:

Haemoscope Corporation
Niles IL 60714 USA

800-GET-A-TEG / 800-438-2834
847-588-0453
Fax: 847-588-0455
Web: www.haemoscope.com
E-mail: info@haemoscope.com

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Thrombelastograph® and TEG® are registered trademarks, and TAS™, Guide™, and PlateletMapping™ are trademarks of Haemoscope Corporation. Other products mentioned are trademarks of their respective companies.

End of Life - The life cycle of the TEG analyzer is seven years. Please do not discard or recycle. Contact your Haemoscope representative for information about sending your machine back to Haemoscope for proper disposal.

INDICATIONS FOR USE

The TEG system is a non-invasive diagnostic instrument designed to monitor and analyze the hemostasis state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The TEG system is indicated for use with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and/or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.

INTENDED USE

The TEG system is intended to be used in vitro to provide a quantitative and qualitative indication of the hemostasis state of a blood sample by monitoring, measuring, analyzing and reporting hemostasis parameter information. The TEG analyzer records the kinetic changes in a sample of whole blood, plasma or platelet rich-plasma as the sample clots, retracts and/or lyses (breaks apart).

Results from the TEG analyzer should not be the sole basis for a patient diagnosis; TEG results should be considered along with a clinical assessment of the patient’s condition and other coagulation laboratory tests. The TEG analyzer is for Professional Use Only.
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The Thrombelastograph® (TEG®) Hemostasis System 5000 series 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® analyzer is indicated for use with adult patients where an evaluation of their blood coagulation properties is desired. Coagulation evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and/or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.

The TEG® 5000 series analyzer is intended to be used to provide a quantitative and qualitative indication of the coagulation state of a blood sample by monitoring, measuring, analyzing, and reporting coagulation parameter information. The TEG® analyzer records the kinetic changes in a sample of whole blood, plasma or platelet rich-plasma as the sample clots, retracts, and/or lyses (breaks apart).

Results from the TEG® analyzer should not be the sole basis for a patient diagnosis; TEG® results should be considered along with a clinical assessment of the patient’s condition and other coagulation laboratory tests. For Professional Use Only.

This manual describes how to use the Thrombelastograph® (TEG®) Hemostasis System 5000 series and higher using Version 4 TEG Analytical Software (TAS™).

Application of the TEG® analyzer has been described in articles published in many of the most prestigious peer-reviewed journals. All suggested treatments are based on the experiences of clinicians who have used them successfully and published their results. References are found at the end of each chapter.

This introduction outlines some of the various analytical techniques that can provide additional information on a blood sample. Most of the techniques
have evolved from over 1000 research publications in the last 20 - 30 years, with the greatest increase in applications occurring in the last five years. The most outstanding results have been demonstrated for the management of hemostasis during major surgical interventions such as liver transplants and cardiopulmonary bypass procedures. Concomitantly, recent advances in the understanding of the biochemistry of coagulation have supported the advantages of whole blood TEG® analysis by demonstrating the role of cell surfaces in localization, amplification, and modulation of coagulation functions\(^1\). As a result of this knowledge, the TEG® analyzer has evolved from a research tool into a powerful clinical monitor to evaluate the interaction of platelets and plasma factors, plus any additional effects of other cellular elements (e.g., WBCs, RBCs, etc.) with the activities of the plasma factors.

The discussion of the techniques will be centered around their current application to liver transplantation and cardiopulmonary bypass. The most commonly used sample types and techniques and their advantages are listed later in table 1 on page 11.

The TEG® system is comprised of the TEG® Hemostasis System together with the TEG® Analytical Software. This package provides breakthrough capabilities such as simultaneous analysis of up to eight samples, automatic calculation of a wide range of coagulation parameters, and data management facilities. The software can be run in a configuration that allows the analyzer to be placed in a centralized location such as a laboratory, with results displayed where needed, for example, in remote operating rooms. A full description of the TEG® Analytical Software can be found beginning in Chapter 4.

**TEG® Design Principles**

*The TEG® analyzer’s approach to the monitoring of patient hemostasis is based on these two facts:*

1. *The end result of the hemostasis process is a single product — the clot.*
2. *The clot’s physical properties (rate, strength, and stability) will determine whether the patient will have normal hemostasis, will hemorrhage or will develop thrombosis.*
The TEG® analyzer measures the clot’s physical property by the use of a special stationary cylindrical cup that holds the blood and is oscillated through an angle of 4°45’ (Figure 1.1). Each rotation cycle lasts 10 seconds. A pin is suspended in the blood by a torsion wire and is monitored for motion. The torque of the rotating cup is transmitted to the immersed pin only after fibrin-platelet bonding has linked the cup and pin together. The strength of these fibrin-platelet bonds affects the magnitude of the pin motion, such that strong clots move the pin directly in phase with the cup motion. Thus, the magnitude of the output is directly related to the strength of the formed clot. As the clot retracts or lyses, these bonds are broken and the transfer of cup motion is diminished.

The rotation movement of the pin is converted by a mechanical-electrical transducer to an electrical signal which can be monitored by a computer.

The resulting hemostasis profile is a measure of the time it takes for the first fibrin strand to be formed, the kinetics of clot formation, the strength of the clot (in shear elasticity units of dyn/cm²) and dissolution of clot (Figure 1.2).
Performance Characteristics and Specifications

Performance characteristics and specifications for the TEG® analyzer are detailed in Appendix A.

TEG® Theory

The computerized Thrombelastograph® Hemostasis System (TEG®) automatically records the kinetic changes in a sample of whole blood, plasma, or platelet-rich-plasma as the sample clots, retracts and/or lyses (breaks apart). The resultant coagulation profile is therefore a measure of the kinetics of clot formation and dissolution and of clot quality.

The TEG® analyzer monitors shear elasticity, a physical property of a blood clot, and is, therefore, sensitive to all the interacting cellular and plasmatic components in the blood that affect the rate or structure of a clotting sample and its breakdown. The clot's ability to perform useful mechanical work (the work of hemostasis) is a function of the net result of the interactive coagulation proteins and cellular elements involved in the process of hemostasis. In essence, the TEG® analyzer measures the ability of the clot to perform mechanical work throughout its structural development.

The overall coagulation profile can be qualitatively or quantitatively interpreted in terms of the hypo-, normal, or hypercoagulable state of the sample and the degree of lysis.

TEG® Parameters

To evaluate the graphic information displayed by the TEG® analyzer, five main parameters of clot formation and lysis are measured (See Figure 1.2):
The four coagulation parameters R, K, α, MA can be combined to yield indices of coagulability, while additional measurements can be made to evaluate other aspects of the coagulation profile such as time to MA and time to lysis as described below.

R or R-Time
Reaction Time. The time from the start of a sample run until the first significant levels of detectable clot formation (amplitude = 2mm in the TEG® tracing). This is the point at which most traditional coagulation assays reach their end-points. R-time is prolonged by anticoagulants and factor deficiencies and shortened by hypercoagulable conditions.

K or K-time
Achievement of a certain clot firmness. The time from the measurement of R (beginning of clot formation) until a fixed level of clot firmness is reached (amplitude = 20 mm). Therefore, K-time is a measure of the speed or clot kinetics to reach a certain level of clot strength. K is shortened by increased fibrinogen level and, to a lesser extent, by platelet function, and is prolonged by anticoagulants that affect both. If the amplitude does not reach 20mm, K is undefined. If the MA of the sample is less than 25 mm, do not use K for clinical decisions. In these samples, use angle.

Angle (α)
The kinetics of clot development. The angle is closely related to K-time, since they both are a function of the rate of polymerization. The angle is more comprehensive than K-time, since there are hypocoagulable conditions in which the final level of clot firmness does not reach an amplitude of 20 mm (in which case K is undefined). Similar to K, α is larger by increased fibrinogen levels and, to a lesser extent, by platelet function, and is decreased by anticoagulants that affect both.

MA
Maximum Amplitude. Measurement of maximum strength or stiffness (maximum shear modulus) of the developed clot. Clot strength is the result of two
components — the modest contribution of fibrin to clot strength and the much more significant contribution of the platelets.

Other clot formation parameters

In addition to the major parameters just described, several others can aid in determining clot kinetics, strength, and stability:

- projection of MA expressed as the PMA parameter
- time to MA expressed as the TMA parameter
- amplitude, clot strength at a specific time expressed as the A parameter
- shear elastic modulus strength expressed as the G and E parameters
- thrombodynamic index expressed as the TPI parameter

Additional coagulation parameters describing thrombus formation expressed as velocity (first derivative) parameters are discussed below in the section named “Velocity (First Derivative) Parameters” on page 11.

PMA

PMA - Projected MA, an estimator of MA, that is, whether the MA value will achieve at least the lower limit of the normal value for samples treated with Kaolin or Celite (see the section named “Blood sample types” later in this chapter). PMA facilitates earlier detection of platelet dysfunction and earlier therapy decisions before MA is available.

PMA begins to display when amplitude reaches 5 mm, and is finalized when the rate of clot formation slows ($\alpha$ is final). PMA is displayed as either:

- 0 (to indicate that it is likely that MA will reach the lower limit of normal)
- 1 (MA is unlikely to reach the lower limit of normal).

Once the MA value approaches the lower limit of normal, it should be used for evaluation instead of PMA.

Time to MA

TMA - Time to MA, a global measurement of the dynamics of clot kinetics. TMA combines the rate of clot development from the start of a sample run until the clot reaches its maximum strength. This can be described as the time needed to form a stable clot.

A parameter

The A parameter measures the width of the tracing at the latest time point. It is equal to MA until MA is determined. Amplitude (A) is a function of clot strength or elasticity and is measured in mm.

G parameter

The A parameter can be transformed into the actual measure of clot strength (G) (shear elastic modulus strength, SEMS) and is measured in dyn/cm² divided by 1000 (displayed in the software as Kd/sc). The absolute SEMS of the sample can be calculated from A as follows:

$$G = \frac{5000A}{(100-A)}/1000$$
Note that A is equal to MA until MA is reached, at which time calculation of G stops. The elastic shear modus G of the sample increases exponentially in proportion to the amplitude (A) of the TEG® tracing.

An amplitude of 50 mm (normal value of whole blood) corresponds to a SEMS of 5000 dyn/cm². An increase in A from 50mm to 67 mm is equivalent to a two-fold increase in the SEMS. Thus, the G parameter not only provides a measurement of clot firmness in force units, but also is more indicative of small changes in the clot strength or clot breakdown than is the amplitude in mm because it is an exponential reflection of A.

E is a normalized G parameter and is referred to as an elasticity constant. In the formula, 5000A is replaced with 100A. (Note that A is equal to MA until MA is reached.) The rationale behind this index is that at the amplitude of 50 mm (normal value of whole blood), the E is \( (100 \times 50)/(100-50) = 100 \). Therefore E provides a relative elastic scale in which a normal clot with a maximum elastic modulus of 50 mm is given an elastic modulus of 100. E is expressed as dyn/cm².

\[ TPI = \frac{EMX}{K} \]

where EMX is E at maximum amplitude (MA), i.e., \( EMX = \frac{(100 \times MA)}{(100-MA)} \), and K is measured in mm. This parameter was proposed by Raby²,³. According to Raby², TPI describes the patient's global coagulation whether the patient is normal coagulable (TPI between 6 - 15), hypocoagulable (TPI < 6), or hypercoagulable (TPI >15), when using sodium citrated native whole blood. The utility of this parameter is demonstrated by Szefner et al³ and Copeland et al⁴ in the monitoring of the hemostasis of patients undergoing total artificial heart or heart assist device implantation.

A Coagulation Index (CI) that describes the patient's overall coagulation is derived from the R, K, MA and Angle (α) of native or kaolin/celite-activated whole blood tracings.

Normal values for the Coagulation Index lie between -3.0 and +3.0, which is equivalent to three standard deviations about the mean of zero.

Positive values outside this range (CI > +3.0) indicate that the sample is hypercoagulable, whereas negative values outside this range (CI < -3.0) indicate that the sample is hypocoagulable.

Hypercoagulable conditions like cancer (adenoma) or monitoring deep-vein thrombosis are detected at CI values of +5.0 and above⁸,⁹.

Preliminary equations involving whole blood, celite- or kaolin-activated whole blood, or both combined are available⁷,⁸. The equations should be validated before applying them clinically. Since the normal range of sodium citrated
blood is very similar to non-citrated blood, the same coefficients are applied to sodium citrated native and celite blood as best estimates.

The equation for the TEG® coagulation indices are simple linear combinations of the variables as follows:

<table>
<thead>
<tr>
<th>Index</th>
<th>Equation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native Whole Blood CI</td>
<td>$CI = -0.2454R + 0.0184K + 0.1655MA - 0.0241c - 5.0220$</td>
</tr>
<tr>
<td>Celite-activated WB CI</td>
<td>$CI = -0.6516R_c + 0.3772K_c + 0.1224MA_c + 0.0759c - 7.7922$</td>
</tr>
<tr>
<td>Combined</td>
<td>$CI = -0.112R - 0.222K + 0.040MA - 0.042c - 0.578R_c + 0.370K_c + 0.111MA_c + 0.097c - 8.397$</td>
</tr>
</tbody>
</table>

Note: R and K values must be in min. Parameters that have the subscript “c” are measured for Celite-activated samples. Also note: when MA < 20 mm, K is undefined and CI is not calculated.

Cohen et al. compared TPI with CI in a study involving cancer patients, and found that the CI is very close to TPI, but is a slightly better discriminator between hyper- and normal coagulable in this population. This is perhaps due to the contribution of the R and $\alpha$ parameters in the CI equation.

## Clot Lysis Parameters

Several methods have been proposed to evaluate clot lysis.

It should be noted that a clinical fibrinolytic state involves the presence of tissue plasminogen activator (t-PA), which produces fibrin degradation products. Characteristically, fibrinolysis leads to clot dissolution, depending on the severity and stage (early or late) of the fibrinolytic process. Therefore, several sets of parameters are computed to quantify the fibrinolytic state. They are similar in that they rely on the loss of clot strength with time after the maximum clot strength (MA) is reached:

- reduction in area measurements expressed as the LY30 and LY60 parameters
- reduction in amplitude measurements expressed as A30 and A60 parameters
- estimated percent lysis expressed as the EPL parameter
- clot lysis time expressed as the CLT parameter

### LY30 and LY60

The LY30 and LY60 parameters measure percent lysis at 30 minutes and 60 minutes after MA is reached. The LY30 and LY60 measurements are based on the reduction of the area under the TEG® tracing from the time MA is measured until 30 (or 60) minutes after the MA.
The A30 and A60 parameters are the amplitudes of the TEG® tracing at 30 minutes and 60 minutes after MA is measured.

A30 and A60 are point measurements that look only at the TEG® tracing amplitude A at 30 and 60 minutes after MA. LY30 and LY60, on the other hand, are measures of the area under the TEG® tracing, and, therefore, contain more information because they look at the entire tracing between MA and 30 (or 60) minutes after MA.

A30 and A60 are sometimes presented in an alternate form called the Whole Blood Clot Lysis Index (CL30 or CL60), which presents the values of A30 or A60 relative to MA. The formulas are:

\[
\begin{align*}
\text{CL}_{30} &= 100 \times \left( \frac{A_{30}}{MA} \right) \\
\text{CL}_{60} &= 100 \times \left( \frac{A_{60}}{MA} \right)
\end{align*}
\]

The smaller the value of CL30 or CL60, the greater the severity of the fibrinolytic process. Note that CL30 and CL60 measure fibrinolysis inversely to the way it is measured by the LY30 and LY60 parameters. Generally, when LY30 and LY60 are high (i.e., fibrinolytic activity is high), CL30 and CL60 are low, and vice versa.

You can convert CL30 or CL60 to be proportional to the level of fibrinolytic activity with the formula:

\[
\begin{align*}
\text{CL}_{30} &= 100 - \text{CL}_{30} = 100 \times \left( MA - A_{30} \right) / MA \\
\text{CL}_{60} &= 100 - \text{CL}_{60} = 100 \times \left( MA - A_{60} \right) / MA
\end{align*}
\]

The two TEG® tracings in Figure 1.3 illustrate the significance of the LY parameters relative to the CL parameters:

![Figure 1.3. CL30 parameter](image)

Thirty minutes after MA is reached, the amplitudes of both tracings read zero due to fibrinolytic activity. Therefore, using the formulas on the previous
page, the CL30 parameter for both tracings is zero. In this instance, the CL30 parameter is of no use in differentiating the two tracings.

However, the LY30 parameters for the two tracings are radically different. In the top tracing, the shaded area under the curve is approximately 15% of the rectangular area. (The rectangle represents the area under the curve if there had been no fibrinolysis.) Thus, LY30 is approximately 85%. In the bottom tracing, the shaded area comprises about 85% of the rectangle. This makes the value of LY30 approximately 15%.

Thus, CL30 and CL60 represent point measurements of the fibrinolytic status at exactly 30 and 60 minutes after MA is achieved. LY30 and LY60 represent the fibrinolytic process that took place during those 30 or 60 minutes.

The lysis parameters are illustrated in Figures 1.2 and 1.3

<table>
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</tr>
</thead>
<tbody>
<tr>
<td>Estimated Percent Lysis (EPL) is the estimated percent lysis at 30 minutes after MA. This parameter is computed 30 seconds after the MA, and is continually updated until 30 minutes after MA is reached, when EPL becomes equal to LY30. This parameter gives an idea of the percent lysis prior to 30 minutes after MA. EPL is computed by finding the slope connecting MA to any point between MA and 30 minutes after, then extrapolating to A30. EPL is then $100(\text{MA} - \text{A}_{30})/\text{MA}$, until A30 is reached and it becomes equal to LY30.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clot Lysis Time</th>
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<tbody>
<tr>
<td>Clot Lysis Time (CLT) is the elapsed time between MA and 2 mm amplitude or less post MA.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Lysis Time Estimate</th>
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<tbody>
<tr>
<td>Lysis Time Estimate (LTE) is an estimate of CLT. It is computed 30 seconds after MA and is continually updated until 60 minutes after MA or when an amplitude is reached, whichever comes first. If LTE is greater than three hours, the value is displayed as &quot;&gt;3 hrs.&quot; LTE is derived by calculating the slope of the tracing and extrapolating to an amplitude of 2 mm.</td>
</tr>
</tbody>
</table>
A set of parameters are also generated from the mathematical first derivative of the standard TEG tracing. These parameters describe the formation of the thrombus, as well as the lysis of the thrombus.

### Parameter Definition

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMRTG</td>
<td>Time to maximum rate of thrombus generation</td>
</tr>
<tr>
<td>MRTG</td>
<td>Maximum rate of thrombus generation</td>
</tr>
<tr>
<td>TG</td>
<td>Total thrombus generated</td>
</tr>
<tr>
<td>TMRL</td>
<td>Time to maximum rate of lysis</td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum rate of lysis</td>
</tr>
<tr>
<td>L</td>
<td>Total lysis</td>
</tr>
</tbody>
</table>
Blood Sample Types

The following sections describe the various sample preparations that can be used with the TEG\textsuperscript{®} analyzer and the conditions under which to use the different blood modifiers. The actual sample preparation for analysis is described in Chapter 11.

Table I

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Blood/Reagent</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native</td>
<td>Native whole blood (NWB)</td>
<td>Global evaluation of coagulation</td>
</tr>
<tr>
<td>Activated</td>
<td>NWB &amp; Celite, TF, Kaolin, Thrombin, DAPTTIN, etc.</td>
<td>Speed analysis</td>
</tr>
<tr>
<td>Antifibrinolytic</td>
<td>WB &amp; (\alpha)ACA, Aprotinin, Tx</td>
<td>Reverse fibrinolysis</td>
</tr>
<tr>
<td>drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heparinase</td>
<td>WB &amp; Heparinase</td>
<td>Reverse heparin effects</td>
</tr>
<tr>
<td>Citrated</td>
<td>Citrated WB (CWB)</td>
<td>Prolonged storage</td>
</tr>
<tr>
<td>Activated citrated</td>
<td>CWB &amp; Celite, Kaolin, TF, Thrombin, DAPTTIN, etc.</td>
<td>Speed analysis</td>
</tr>
<tr>
<td>PRP</td>
<td>Citrated Platelet Rich Plasma</td>
<td>Enriched platelet function</td>
</tr>
<tr>
<td>PPP</td>
<td>Citrated Platelet Poor Plasma</td>
<td>Plasma coagulation</td>
</tr>
<tr>
<td>Platelet blockers</td>
<td>WB &amp; ReoPro, Integrilin, Aggrastat, etc.</td>
<td>Reduced or abrogated platelet function</td>
</tr>
</tbody>
</table>

Native Whole Blood Coagulation Samples

In general, the basic TEG\textsuperscript{®} measurements of kinetics, strength and stability of a coagulum can be determined by using a native whole blood sample. This method has provided the most sensitive method for monitoring hypercoagulation or fibrinolytic conditions.

This type of sensitivity does not mean this sample type is the most practical, and we will see how more practical techniques can provide similar results.

Modified Native Whole Blood Samples

Native whole blood samples can be modified by addition of reagents to the \textit{in vitro} sample to determine if a possible therapy might be effective for a coagulopathy, to improve speed of analysis, or to reverse a clinical condition (e.g., heparinization).

These techniques involve addition of the following reagents to the native whole blood sample:

- Activators (Kaolin, Celite, tissue factor, thrombin, DAPTTIN, etc.)
- Heparin neutralizers (Heparinase, protamine)
Platelet blockers (ReoPro®, Integrilin®, Aggrastat®, etc.)

Antifibrinolytic drugs (Epsilon-amino-caproic acid, tranexamic acid, aprotinin)

Celite- or Kaolin-activated TEG® methods are used to reduce variabilities and to reduce the running time of a native whole blood TEG® sample by as much as half—except for patients on aprotinin (Trasylol). Celite, silica particles (diatomaceous earth), shortens coagulation time because it acts as a contact surface activator (intrinsic pathway), which activates Factor XII and platelets and stimulates the reserve clotting ability of a blood sample. Similar to celite is kaolin (hydrated aluminum silicate), which also activates the intrinsic pathway via Factor XII.

Tissue Factor (TF) is an enzyme that, together with factor VII, shortens coagulation time by activating factors IX and X (extrinsic pathway).

Thrombin is an enzyme that shortens coagulation time (common pathway) by cleaving fibrinogen to form the fibrin clot, and activates platelets.

Heparin Neutralizers

Heparinase I, from Flavobacterium heparinum, is an enzyme that rapidly and specifically neutralizes the anticoagulant properties of heparin. Heparinase acts by cleaving the heparin molecule into small inactive fragments without affecting the function of other blood components involved in coagulation.

Adding heparinase to the blood allows visualization of any developing coagulopathies during perioperative cardiopulmonary bypass that are masked by high levels of therapeutic heparin or are masked by heparin released from the mask cell of the donor liver during liver transplantation.

Compare the R parameter of heparinase-modified TEG® samples and non-heparinase-modified samples for patients undergoing cardiopulmonary bypass surgery or liver transplantation. If the R parameters are the same, enough protamine was given to neutralize all administered heparin, in the case of CPB or endogenic heparin during liver reperfusion stage.

Heparinase also eliminates any problems or concerns associated with drawing blood from a heparinized line. Under these circumstances, heparinase will correct, in vitro, a prolonged onset of clotting compared to a control sample.

Platelet Blockers

Since all platelet-fibrin(ogen) interaction is mediated by the platelet integrin GPIIb/IIIa receptor, it is possible to negate the platelet contribution to TEG® tracing with anti-platelet drugs such as c7E3 Fab (ReoPro®), an antibody fragment that inhibits clot retraction and abolishes platelet aggregation by binding to fibrin(ogen) receptors GPIIb/IIIa on platelets. Adding a platelet blocker drug to a whole blood sample can be used to measure the effect of platelets on the TEG® profile.
Antifibrinolytic Drugs

Adding Amicar or the more powerful tranexamic acid or aprotinin (Trasylol) in vitro to a whole blood sample has been used to identify how a previously identified fibrinolytic TEG® profile will respond to this inhibitor. The concentration of antifibrinolytic agents used in vitro are in proportion to the recommended in vivo therapy. Aprotinin inhibits activation of kallikrein and will cause some anticoagulation of the TEG® profile with celite activated samples. Specifically, aprotinin will increase the R parameter by approximately 10 percent, unless the sample is drawn within 30 minutes of a high loading dose (2.0 million KIU). For samples drawn after 30 minutes of high-dose aprotinin, you may see the R as a straight line; therefore, it is better to use kaolin, which is not affected by aprotinin, instead of/in addition to treating samples with celite.

Sodium-Citrated Whole Blood Samples

Citrated TEG® samples are used for conditions where it is difficult to transport the native or modified whole blood to the TEG® sample within four to six minutes of phlebotomy. The citrated TEG® sample requires a citrated whole blood specimen, which is recalcified at some later time. See the section on preparing sodium citrated samples, beginning on page 135 named “Citrated Whole Blood TEG® samples.”

Sodium citrated techniques are also useful when using differential centrifugation to isolate platelet-poor plasma (PPP TEG®) or platelet-rich plasma (PRP TEG®). Normal ranges can be established for each of these analyses so that the specific attributes of coagulation can be monitored.

A good example of this technique is to run a whole blood and a PPP TEG® tracing. The differences in these two tracings are the result of removing the cellular elements such as the platelets. This is an excellent way of quantifying the effects of the platelets. However, using ReoPro, Integrilin, or Aggrastat in vitro, you can accomplish the same without the need for centrifugation.

Finally, all the modified native whole blood techniques can also be applied to a citrated whole blood sample.

Data Analysis

The TEG® tracing can be qualitatively or quantitatively analyzed. The patterns are easily interpreted without measurement to determine conditions of hyper-, hypo-, normal coagulation, and fibrinolysis. However, by using the measurements and established normal ranges and indices, the patterns can be quantified as to the degree of abnormality, as described in Chapter 2. This allows therapies to be judged for their effectiveness in correcting a pathological state.
Qualitative Analysis

**Normal**
R;K;MA;Angle = Normal

**Anticoagulants/hemophilia**
Factor Deficiency
R;K = Prolonged;
MA;Angle = Decreased

**Platelet Blockers**
Thrombocytopenia/
Thrombocytopathy
R ~ Normal; K = Prolonged;
MA = Decreased

**Fibrinolysis (UK, SK, or t-PA)**
Presence of t-PA
R ~ Normal;
MA = Continuous decrease
LY30 > 7.5%; WBCLI30 < 97.5%;
Ly60 > 15.0%; WBCLI60 < 85%

**Hypercoagulation**
R;K = Decreased;
MA;Angle = Increased

**D.I.C**

**Stage 1**
Hypercoagulable state with secondary fibrinolysis

**Stage 2**
Hypocoagulable state
References


Hemostasis is a dynamic, extremely complex process, involving many interacting factors, which include coagulation and fibrinolytic proteins, activators, inhibitors, and cellular elements (e.g. platelet cytoskeleton, cytoplasmic granules and platelet cell surfaces).

The ideal way to treat a bleeding or prothrombotic patient is to measure the net product of the multitude of the interacting factors and cellular elements and their interactions in the shortest time possible.

Without this, the clinician has no choice but to use prophylactic drugs in spite of the cost and possible side effects to reduce the probability of coagulopathy, and when coagulopathy does occur he is compelled to do guess work or to give a variety of blood components and hope the result is positive. Researchers and clinicians have been looking for a way to effectively measure and treat patient hemostasis and to enable them to monitor a new class of platelet blockers that have either recently been introduced or are being evaluated.

However, the clinician can be provided with precise information to properly treat the bleeding or clotting patient most effectively and in the shortest time possible if the following is considered:

The tools (or variations of these) available to the clinician for the treatment of coagulopathy are as follows:

- **Blood components:**
  - Fresh frozen plasma (FFP)
  - Cryoprecipitate (cryo)
  - Platelets
Antifibrinolytic drugs:
- Aminocaproic acid (Amicar®)
- Aprotinin (Trasylol®)
- Tranexamic acid (Tx)

Thrombolytic drugs:
- rt-PA
- Urokinase
- Streptokinase

Platelet blocker drugs:
- ReoPro®
- Integrilin®
- Aggrastat®
- Plavix®
- Aspirin
- Etc.

Functional Hemostasis

Despite the many components entering into hemostasis, two facts override all others:

- The end result of the hemostasis process is a single product — the clot.
- The clot is a mechanical device.

The resulting clot

Once the coagulation cascade is activated, whether through the intrinsic pathway, the extrinsic pathway, or a combination of both, thrombin is formed. The thrombin cleaves soluble fibrinogen into fibrin monomers, which spontaneously polymerize to form protofibril strands that undergo linear extension, branching, and lateral association leading to the formation of a three-dimensional network of fibrin fibers. A unique property of this network structure is that it behaves as a rigid elastic solid, capable of resisting the deforming shear stress of flowing blood.

Resistance to the deforming shear stress of the network of fibrin fibers is enhanced further by platelets, which are also activated by thrombin.

Platelets achieve this in two ways:
Platelets enhance fibrin polymerization by acting as nodes or network branch points. They stabilize and significantly enhance the structure rigidity of the fibrin network.¹

Platelet GPIIb/IIIa receptors bind the polymerized fibrin network to the platelets’ actin cytoskeleton. Actin is a muscle protein that has the property of transmitting contractility force. Platelets, through GPIIb/IIIa receptor, transmit their contractility force to the fibrin network by exerting a “tugging” force and thus affect the mechanical strength of fibrin.¹ The contractility force is the major contributor to the strength of the clot.¹,¹⁰ Therefore, the end result of the activated hemostasis is the fibrin strand, which, together with activated platelets, via GPIIb/IIIa receptors, forms fibrin-platelet bonding to produce the final clot.

The kinetics, strength, and stability (rate of dissolution) of the clot, that is, its physical properties to resist the deforming shear stress of the flowing blood, determine its capacity to do the work of hemostasis, which is to stop hemorrhage and prevent thrombosis. In essence, the clot is a damage-control device, a temporary stopper, which gradually dissolves during vascular recovery.

The clot is the elementary machine of hemostasis, and the TEG® analyzer measures the ability of the clot to perform mechanical work throughout its structural development.²

The TEG® analyzer, using a small blood sample of whole blood, measures the net product of the interaction of platelets with protein coagulation cascade from the time of placing the blood in the TEG® analyzer until initial fibrin formation, clot rate, strengthening, and fibrin-platelet bonding via GPIIb/IIIa, to eventual clot lysis. Time, rate, strength, and stability of clot indicate whether the patient has normal, hypo-, or hypercoagulable hemostasis, and provide an indication of treatment necessary to normalize it. The following section explains in detail how this is done.

Each TEG® parameter, R, K, α, MA and LY30, represents a different aspect of the clot’s physical properties. However, due to the interactive nature of hemostasis, these parameters are interrelated. In general, an elongated R means that it takes longer for the first fibrin strand to be formed and therefore an elongated R represents a deficiency in coagulation factors, inhibitors, and/or activators, which results in a slow rate of thrombin generation.

The α parameter measures the rapidity (kinetics) of fibrin buildup and cross-linking, that is the speed of clot strengthening. K, or K time, is a measure of the rapidity of reaching a certain level of clot strength (20 mm amplitude). K and α both measure similar information and both are affected by the availability of fibrinogen, which determines the rate of clot buildup, and, to a
lesser extent, by platelets. Therefore, an elongated K and a reduced α represents a low level of fibrinogen. According to Kang, six units of cryo increased fibrinogen level by 37 ml/dl and increased clot formation rate, α, by 9.4 degrees. MA measures the strength of clot and is affected by platelet number and function and, to a lesser extent, by fibrinogen level. Therefore, a small MA and normal R, K, and α represents thrombocytopenia or platelet dysfunction. According to Kang’s study mentioned above, ten units of platelets increased platelet count by 40,200±31,400/mm³ and increased MA by 13.2mm³. However, MA, K, and α are interrelated due to the interaction between fibrinogen fiber and platelets, which together form the fibrin-platelet bonding to produce the final clot. A low level of fibrinogen will be compensated for, to some extent, by a high level of platelet function, and vice versa.

All studies in the above-cited references were conducted on patients undergoing liver transplantation or cardiopulmonary bypass, and native blood samples were used.

LY30 greater than 7.5% represents hyperfibrinolysis.

Note: In our analyses we assume that the patient is not being treated with heparin or low molecular weight heparin. If he is, then the TEG® sample should be treated with heparinase to neutralize the effect of heparin.
A TEG® schematic output demonstrates the above and the interactive nature of hemostasis:

Let’s assume that tracing 1 represents a normal tracing; therefore, if the patient is bleeding profusely in the presence of a fully functional clot, the reason most likely is surgical. Tracing 2 is the same as 1 as far as K, α, MA and LY30, but the R is elongated. However, tracing 2 is seldom seen clinically because of the interactive nature of hemostasis. If R is elongated, thrombin rate production is so slow that α, K, and MA will be affected. Keep in mind that thrombin, in addition to cleaving fibrinogen into fibrin, also is the most potent platelet activator on whose surface the enzymatic reaction occurs. Therefore, in the presence of such an elongated R, more often the resulting tracing will be similar to tracing 3. The elongated R has to be corrected first. Ten to fifteen minutes post-transfusion another sample is run to determine the effectiveness of the treatment and to further evaluate the resulting tracing.

In tracing 4, the R is slightly elongated but MA is very small. The slight elongation of R is due to the fact that platelets provide the surface where the enzymatic reaction takes place. Therefore, it appears likely that proper treatment such as platelets will normalize R as well as MA.

Similarly, in the case of tracing 5, a typical primary fibrinolysis pattern, where the R is slightly elongated and the MA is small and decreasing, fibrinolysis has to be treated before evaluating R, K, α, and MA, unless these parameters show hypercoagulability, where R and K are small, and MA and α large. In this case, the fibrinolysis is referred to as secondary fibrinolysis, in that it is secondary to hypercoagulability, and an antifibrinolytic agent is contraindi-
cated, since, in these circumstances, fibrinolytic activations prevents microvascular fibrin deposit. In such cases, depending on the clinical situation, hypercoagulability may be treated with anticoagulant drug therapy.

**TEG® Runs**

There are two ways to run TEG® samples, depending on the number of columns available.

One is a “stepwise” approach (described in the previous section) where samples are run one after the other, in a specific order, to identify and treat stepwise the conditions encountered.

The other is a “simultaneous” approach where a number of samples are run at the same time:

1. With different reagents to enable the clinician simultaneously to evaluate and treat the parameters independently of each other, and/or
2. For differential diagnosis, a TEG® sample of untreated blood is superimposed or analytically compared to a blood sample treated in vitro with blood components, e.g., fresh frozen plasma, cryoprecipitate, platelets, or pharmacological agents, e.g., amicar or protamine sulfate. These tracings can easily differentiate in vitro which treated sample produces a normal tracing, and indicates which treatment will likely cause a similar effect in vivo.

---

**Differential Diagnosis (Simultaneous Runs)**

This section describes a strategy for performing differential diagnosis using the simultaneous samples technique and the TEG® Analytical Software to allow easy identification of therapy.

By adding blood components such as FFP or platelets, or pharmacological agents such as amicar or heparinase to patient blood samples, you can use the software to help you determine which treatment will be most effective.

Note that Chapter 4, “Looking at TEG® Data” begins the description of the use of the software in detail. The following description is meant only to illustrate the example.

For example, suppose that a patient sample produces a tracing as shown next:
A qualitative inspection of this tracing, using the guidelines given earlier on page 14, invites a diagnosis of fibrinolysis. Earlier sections describe treatment with blood components or pharmacological agents under these conditions. Therefore, in vitro, you could run several samples, perhaps adding FFP to one sample, amicar to another, and platelets to still another. Suppose the amicar-treated sample produced the tracing shown in figure 2.3. This tracing appears to approach normal values.

The TEG® Analytical Software can store normal tracings that can then be superimposed on patient tracings for comparison. If we superimpose the normal tracing on top of both the patient tracings shown in figures 2.2 and 2.3, we see the following result:
You can see that the amicar-treated blood sample produces output that closely matches the normal values.

Exercises in the analysis of TEG® tracings can be found on the Internet Journal of Anesthesia, which can be accessed from Haemoscope’s web site at:

www.haemoscope.com/pubinet.html

or directly at:

www.ispub.com/journals/IJA/Vol1N3/teg.htm


Introducing the TEG® Software

The TEG® Analytical Software (TAS™) is distributed in two versions:

- TEG-enabled, for operators who will be running TEG® samples
- Remote (TEG-disabled), for clinicians and others who will be viewing or otherwise dealing with data generated by the TEG® analyzer.

The only difference between the two versions is that the TEG-enabled version contains the features needed to run and maintain the TEG® analyzer, while the remote version does not. Specifically, the remote version cannot start or stop a TEG® sample, nor can it run maintenance procedures such as test checking or calibration. The menu items and/or icons for these features are not included in the remote version. Otherwise, the two versions of TAS™ are identical in their appearance and functionality.

This chapter describes some general concepts about the TEG® Analytical Software (TAS™). In particular, we describe the capabilities of the software and different types of users.

Program features are documented in the chapters that follow. If you will be running samples, i.e., the TEG-enabled version, we recommend that you familiarize yourself with the section titled “TEG-enabled version” beginning with Chapter 10.

TAS™ has application in multiple scenarios where the tasks to be carried out are different, depending on the user, for example:

- A “clinician” viewing TEG® sample data during a clinical/surgical procedure
- An “operator” (who could be a doctor, nurse, technician, or other trained staff) using the software while connected to a TEG® analyzer running samples
A “researcher” reviewing data and, possibly, exporting results for use in a presentation or for analysis.

While we suggest that all users read all chapters, this manual is written such that, depending on what you need to do with TAS™, you can read certain chapters and skip others. See the following table of chapters dealing with the software for typical reading patterns:
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<thead>
<tr>
<th>Chapter</th>
<th>Feature</th>
<th>Typical User</th>
</tr>
</thead>
</table>
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       | ▶ Viewing tracings and printing reports  
       | ▶ Adding notes and other data  
       | ▶ Tracing maximized to full screen  
       | ▶ Superimposing multiple tracings  
       | ▶ Guide™  
       | ▶ Filtering which samples are displayed | ▶ Clinicians  
       | ▶ TEG® operators  
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| 5       | ▶ Entering additional laboratory results for a sample  
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| 6       | ▶ Creating and deleting records | ▶ TEG® operators  
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       | ▶ Lab managers |
| 12      | ▶ Starting samples  
       | ▶ Inputting identifying information  
       | ▶ Stopping samples | ▶ TEG® operators  
       | ▶ QA personnel |
| 13      | ▶ Examining the QC database  
       | ▶ The Maintenance screen  
       | ▶ Maintenance history | ▶ TEG® operators  
       | ▶ QA personnel |
Software Overview

TAS™ provides a great deal of flexibility in viewing and managing TEG® samples. TAS™ can be run with or without a TEG® analyzer attached to your computer — for example when you are in an operating suite and viewing tracings generated in a central lab.

The software has the following features:

**For clinicians, operators, researchers:**

- **Selective data retrieval.** You can choose to view all tracings or filter the tracings by multiple criteria including patient name, test result ranges, site (such as OR1, lab, etc.), status (active samples only or all), date, etc. See Chapter 4, page 43.

- **Guide™.** You can overlay patient tracings with tracings of common coagulopathies for comparison.

- **Clot™ graphic.** You can view the TEG® output in an additional graphic format that displays the major clotting and lysis tests in the form of a clot droplet.

- **Projected MA.** The program projects whether the MA will reach the lower limit of normal for certain sample types.

- **Customized sample types and data views.** You can define which tests appear and the order in which tests are displayed. See Chapter 9, page 115.

- **Reference tracings.** You can set a reference tracing (baseline or other) that can be viewed together with other samples for that patient and with normal values for a given sample type. See Chapter 4, page 47.

- **Formatted reports.** The program produces formatted patient reports including all graphical and numeric information about the sample and the patient.

- **User profiles.** You can customize the settings used by the program to your own preferences, saving steps when you are logging in and using the program. See Chapter 9, page 114.

**For researchers:**

- **Data export.** You can export tracings for use in other software packages such as Microsoft Powerpoint or other graphics packages, and can export data for analysis to such packages as Microsoft Excel or Systat. See Chapter 7, page 98.

**For operators:**

- **Entry of related data.** In addition to selectively viewing the data generated by the TEG® analyzer, you can also enter pre-defined commonly used hematologic tests (such as PT, aPTT, etc.,) that correspond to a TEG®
sample, or add other data (such as blood pressure, pulse, medication dosage, etc.). See Chapter 5, page 66.

- Automated biological control data storage. The software automatically stores your quality control samples according to lot number in a separate database to generate reports and facilitate analysis. See Chapter 13, page 161.

- Maintenance history. TAS™ stores the readings taken during maintenance procedures and can produce a report of all maintenance performed on the attached TEG® analyzers.

In the management of hemostasis, it is not typical to draw and analyze just one blood sample. Rather, usually a series of patient samples are drawn and analyzed according to a protocol, and the trend of changes from baseline are tracked to evaluate the patient’s hemostasis state and determine appropriate therapy at the appropriate time. In addition, it is not atypical for a patient to have multiple procedures over time.

For these reasons, TAS organizes the data for a patient into "cases," which can be identified by the patient name and ID, together with a procedure name. The procedure names can be defined by the Site Administrator to standardize the data and customize it to your site.

Patient identifying information for samples, both online and on reports, is generally displayed in the form:

Lastname, firstname [procedure]

as in:

Smith, Mary [CABG]

This allows the case data for Mary Smith during her CABG procedure and subsequent intensive care stay to be managed separately from, for example, some other revascularization procedure next year. This also allows "case summary" data to be entered and case reports to be generated in a "case" oriented fashion. It also allows analysis of data outside TAS by statistical systems that is grouped by procedure names.

Since the TEG® analytical software is a Windows-based program, it allows the typical use of keyboard and mouse for inputting data and making selections. However, in some situations, additional input methods might be useful. The TAS™ also supports the use of touch screens and barcode scanners.

TAS™ supports the use of touch screen technology for selection and input of selected information. For example, the touch screen buttons can be pressed to...
navigate between screens, press command buttons, select samples, etc. Textual or numeric information must be entered by way of the keyboard. More information about touch screen use is available as appropriate throughout the next chapters.

**Barcode scanning**

A Windows-supported barcode scanner can be used for inputting patient ID information. This is useful for operators in a laboratory environment where the blood sample may have an alphanumeric barcode affixed to either a tube or syringe to identify the patient. The TEG® software converts the barcode, and associates the ID with a patient record for a sample. Barcode scanning is also available for the Operator ID field. More information about barcode scanning is contained in Chapter 12 on page 148.

**Previous version databases**

Note that if you wish to use databases from previous versions of the TEG software, this is how they are handled:

- **Version 1, version 2 and version 3** databases must be imported into an existing version 4 database. You can create a new version 4 database for the import, as described in Chapter 12, or import into a database that already contains data. The import procedure is documented in Chapter 7.
Remote Version
Looking at TEG® Data

About This Chapter

This chapter describes options available for viewing and printing TEG® data, including using the interpretation Guide™ and the Report option, maximizing tracings, superimposing multiple tracings, and using normal and reference tracings. It also describes how to enter additional information for samples.

This chapter is directed to all user types, but particularly to clinicians and point-of-care users, and assumes you are running the Remote version of the software and will be viewing tracings and data that are being run on another computer. For example, you are in an operating suite and viewing tracings generated in a central lab during a surgical procedure, in the ICU, trauma center, etc, or are reviewing finished tracings for completeness of information, etc.

Please note that some of the features described may not be available to you.

The availability of some features is controlled by the Site Administrator during system setup. For example, some users may only be able to view data, and not have the permission to enter or modify data. See your Site Administrator if you have any questions about this.

TEG® training includes certification that indicates a user is fully knowledgeable about the TEG® analyzer and software and understands all the proper procedures. Any user of the TEG® system must complete this training and achieve certification before running patient samples.

This chapter assumes that the software is installed and operational, and, if you are running on a network and will access a network database, that all the required network connections and drive mappings are in place.
**Start the program**

Double-click on the TEG® software icon to start the program.

![TEG® V4](image)

The icon is accessible either from the Windows Desktop or from the Start Button. First displayed is the splash screen showing the program title and copyright information.

![Figure 4.1. Splash screen](image)

It disappears in a second or two, or you can click on it or press any key to clear it. Next, you must log in to gain access to the system.

**Logging in**

The login screen collects information about the user logging in. You identify yourself with your user name and password, and select the database you will be using. Each of these steps is described in detail in the sections that follow.

*Shortcut tip:* In many cases, just typing the first character of your user name, followed by clicking OK or pressing the Enter key will log you in, set your database, and take you to the Main screen. (If you are set up like this, you can skip to the section named “The Main Screen” on page 39.)
The login screen is shown here:

![Login Screen]

*Figure 4.2. Login screen*

Your user name and password (if any) have been assigned by the local site administrator and determine your personalized settings (referred to here as user preferences or user profile. User preferences are described in more detail in Chapter 9.)

Select your user name from the pulldown list. Usually you can just enter the first character of the name and the right one is displayed in the box. Next, if you were assigned a password, enter it into the password box. The password, if used, is case sensitive. For example, if your password is Lola, you must enter it with the upper case L. When you type the password, it is echoed to the screen as asterisks and is never displayed.

The login process requires that you identify which database you want to access to view, store, or otherwise access patient sample data. Your user profile contains a patient database name, which is displayed when you enter your user id. The database name is not displayed until you click into another text field.

If you wish to use a different database, you can select a different one using one of several methods.

- To access an existing database, type its name, including the path (e.g.,
C:\MYDIR\MYPATIENTS.TEG) into the “Patients database” field, or click the Locate button to search for the database you want.

Clicking on Locate brings up location options including Find, Browse, and Cancel.

- **Find.** Search an entire hard drive for any TEG® databases. To Find databases, select a drive letter and then click on Find to begin the search. If your hard drive is C:, you can click Find without selecting a drive letter first.

Click on the desired database name when it is displayed, then on Done. If your hard drive has many folders and/or files, it may take a few minutes to locate all the databases.
- **Browse.** Browse lets you traverse the directory tree to locate your database.

![Browse for database](image1.png)

Figure 4.6. Browse for database

Use the Windows' standard browse method to find the path and database, first navigating to the drive and folder, then selecting a database name by clicking on it. Then click on Open.

- **Cancel.** Return to the login screen without making a selection.

Once you are logged in, the first data screen you see is the central program screen, referred to throughout as the “Main screen.”

![The Main Screen](image2.png)

Figure 4.7. The Main Screen
You can return to this screen from other places in the program by clicking on the Main button on the local toolbar (see figure 4.7 for local toolbar location)

Figure 4.8 Local Toolbar

Overview
Sample identifying information appears in the center of the screen (see also figure 4.16 below) with corresponding numeric data to its right. (Notice that which tests appear here, as well as the order in which they are shown, is controlled by your user profile, and can be changed as described in Chapter 9.)

The corresponding tracings are displayed at the left. Any tracing can also be maximized to fill the screen (shown in figure 4.17 and described in the section named “Maximized view”).

Local toolbar
The toolbar at the top of the display panel (local toolbar) provides options for changing the size of tracings displayed (Multi and Max) as well as for viewing filtered subsets of the database (Filter, Active, SiteID, and Patient) and displaying the graphic of the clot (Data). You can return to this screen from other views by clicking on Main in the local toolbar.

Numeric data panel
The data panel at the right shows numeric data for the eight tracings at a time. The sample data is arranged by default in order by sample start date/time with most recent samples first. (See the section named Sorting later in this chapter.) The left portion of the panel displays sample identifying information: Channel number with sample type below it, then patient name with a sample description below it. The right portion of the data panel displays the numeric results generated by the analyzer.

Scrolling
You can scroll up and down to view other tracings using the vertical scrollbar (the data scrollbar) and you can horizontally scroll the data panel to see additional tests using the horizontal scrollbar. Clicking on the arrows at the ends of the scrollbars moves either up/down or left/right by one, while clicking in the area between the arrows scrolls a “pageful” at a time, either for the next/previous eight samples (vertical) or five tests (horizontal).

No tracing available
You may see samples that list “No tracing available” in the tracing panel, as shown below in Figure 4.9:

![No tracing available](image)

*Figure 4.9. No tracing available*

Usually, this is an indicator that the record was created manually (as described in Chapter 6 beginning on page 88), and, therefore, that no tracing data exists in the database for that record.

Some numbers in the data panel may be displayed with asterisks (*****) below them. This means that they are temporary (interim) values for which the final data is not yet available. If a sample is a completed sample (white background), the run was terminated before the final values were achieved.

Displaying asterisks for interim EPL and LTE values is optional. The Site Administrator chooses whether or not the asterisks will be displayed.

You may observe a ¶ symbol in front of the sample description in the Main screen (displayed above the tracing in the tracing panel and in the data panel). This is a Notes flag that there is a more detailed comment/note about this case in the Case screen. You can access this information by selecting the sample, then clicking on the Notes button in the main toolbar.

The § symbol is similar to the ¶ symbol in that they both represent notes. The ¶ symbol represents notes that are written at the case level and are used in a more global sense, while the § symbol represents sample notes that represent information relevant to that sample only. You can access this information by selecting the samples, then clicking on the SNotes button in the local toolbar.

The table below lists the meaning of the different background colors of the sample id panel you may see in the main screen:
### Background color | Meaning
---|---
Cyan (blue) | Selected sample. Note that if the sample currently selected is Active, the green “Active” color code at the bottom of the screen flashes slowly.
White | Completed sample or manually created record
Green | Active sample

### Sorting

The data on the screen is sorted by date, with the most recent samples at the top. You can customize this by clicking on any of the column headings to sort on a column. Clicking once sorts in ascending order. Clicking a second time changes the sort to descending order. For example, clicking once on the Patient name heading sorts from A to Z, while clicking a second time changes the sort from Z to A.

### Touch Screen Use

If you will be using a touch screen to perform program operations, clicking on the Touch icon in the main toolbar calls up the Samples information for editing.

![Figure 4.10. Touch screen icon](image)

If you are using a touch screen, when this manual instructs you to click to select an item, you can use the touch screen surface to select instead.

If the touch icon is not enabled (grayed-out), you can enable it by clicking on Options on the Main menu, then on Touch.

![Figure 4.11. Enable touch screen](image)

![Figure 4.12. Enable patient filter](image)
Depending on how databases are used at your site, when the database is opened, you will see either a blank Main screen or one filled with samples that may not be relevant to you. You can easily suppress all data that does not pertain to you by filtering. Three “quick” filters are available: the Patient, Site, and Active filters, and a fourth, user-specified criteria filter.

To filter the database for a specific patient, click on the Patient icon in the local toolbar.

Select the patient from the list, then click Done. The display is now limited to the patient you selected. You can filter further for Site Id and/or sample running (active) status. This can be useful when the patient has had multiple procedures at different times and the data is stored in the same database.

You can select samples for specific sites; for example, suppose you are in OR3 and wish to view only the samples from OR3 for the selected patient. Click on Site in the local toolbar.

This presents a list of the available Sites for selection.

Select OR3, then Done.

The display is now limited to only OR3 samples for the patient you selected.

You can select more than one site by simply clicking on each site you are interested in.
Active filter

If you wish to further filter the display, you can select only active samples by clicking on Active in the local toolbar:

Now the display is limited to OR3 samples that are still running for the patient you selected.

You can also do more advanced filtering of samples by using the Filter button, which lets you select a specific patient, value of TEG® data, date, etc. See the section named “Advanced Filters” on page 69.

To turn off either the Patient, Active, or SiteID filter, click the appropriate icon.

Data/Tracing Views

While the sample is running, data is being collected and the various TEG® tracing parameters are calculated. As this happens, the sample data panel begins to fill with the numerical results at the same time that the tracing panel fills with the graphical results.

![Main screen with tracings and numbers](image)

**Figure 4.16.** Main screen with tracings and numbers

During tracing/data calculation and display, you may notice the most recent points/values change. This is because the most recent one minute's-worth of data are continuously optimized and re-displayed.

Select a sample

To select a sample for further action, click either on the tracing or anywhere in the row of sample identifying information or numeric results.
When you click on either a tracing or sample data, the tracing/data pair is selected and highlighted. The tracing border, the sample ID information, and numerical data receive a cyan blue background. Therefore, if you click on a tracing, its corresponding data is highlighted also, and vice versa, as shown above in Figure 4.16 for Larry Wilson.

When you have selected a sample by clicking either on the tracing or on the data, the status bar at the bottom of the screen displays additional identifying information, as described further on page 68.

You can view sample data in other ways besides the normal eight-up view provided by the Main screen. You can also access:

- Maximized view — enlarged view of one or more tracings, along with their sample data and clot graphic
- Detail view — more detailed information about a single sample, as well as editing mode for sample data

You can enlarge the view of one or more tracings. To maximize a single tracing, either:
- Double-click on a tracing or
- Click on a tracing or sample data, then click Max in the local toolbar.

![Maximized view](image.png)

*Figure 4.17. Maximized view*
The selected tracing is displayed full screen, and a data panel can be displayed containing the numerical data along with an optional clot graphic (see below for explanation) for that tracing. The data panel can be invoked when it is not displayed, by clicking either

- anywhere on the tracing
- on the Data icon in the local toolbar
- or pressing F8

and can be dismissed by clicking on Done.

As you move the mouse over a tracing, the cursor changes to a hand to indicate the tracing is selectable. In addition, you can resize or reposition the data panel as you normally would in Windows, and the program remembers the last position and size, even if you have closed the panel. In addition, your user profile (described in Chapter 9) controls whether the numeric grid and/or clot graphic is displayed in the data panel by default.

The clot graphic

The data panel in Maximized view contains a button named Clot, which expands the data panel to include additional graphical information about the sample. This graphic is called the clot, and is displayed together with a normal representation of the clot to the left, as shown above in figure 4.17 above and figure 4.18 below.

The graphic is only presented for sample types that have normal values for the displayed parameters defined, so if you enter your own sample types without normal values, no clot will be displayed for those sample types.

![Figure 4.18. The clot graphic](image)

The graphic depicts the main parameters for evaluating the hemostasis for that sample. The top portion represents the R (reaction time) value, the middle portion represents the combination of alpha (blue web-like “fibrin”) and MA (green rounded “platelets”), and the lower ring-like portion represents LY30 (percent lysis at 30 minutes). (See Chapter 1 for a description of these measurements.) Each of these four measurements can have one of three levels:

- Low (below normal limit for that sample type)
- Moderate (within normal limits for that sample type)

- High (above normal limit for that sample type)

The R portion of the clot is displayed as soon as interim data is available, the middle section is displayed as soon as the angle is finalized, and the LY30 portion is displayed when an interim value is obtained, and each portion is updated until final values are achieved.

Certain common hemostasis conditions (e.g., hypercoagulability) also cause a textual message to be displayed with the sample clot. (See figure 4.19 below)

If you rest the cursor over any of the three areas of the clot in the “Sample” part of the window, a Windows tooltip appears that tells whether that parameter(s) is within the normal range or not.

![Figure 4.19. Clot with tooltip](image)

The Clot button in the panel toolbar toggles the display of the clot on and off.

Whether the data panel shows the clot by default or not is controlled by the user profile, documented in chapter 9.

A reference tracing is useful as a basis for comparing one sample to another, for example, a baseline sample for a patient to other samples for that patient during a clinical procedure. A tracing is “set” as a reference tracing within this database temporarily for this session and can be reset at any time.

You can set a tracing you are viewing as a reference tracing as follows:

- Click the “Set ref” button in the data panel either in the Main screen or in
Maximized view. (If the data panel is not displayed, you need to display the data panel by clicking on the Data icon in the local toolbar.)

View Reference

In Maximized view, to toggle the display of the reference tracing on or off, click on the Ref button in the local toolbar.

Normal tracing

Normal tracings represent the normal shape of a tracing for a specific sample type and are stored from session to session.

You can save the tracing you are viewing as a normal tracing for that sample type just as you would a reference tracing:

Save Normal

Click the “Save Norm” button in the data panel either in the Main screen or in Maximized view. (If the data panel is not displayed, you need to display the data panel by clicking on the Data icon in the local toolbar.) [Note that if you overwrite a normal tracing, you must re-select the proper one and "Save Norm." In the event you do not have a normal tracing in the database you are using, you can open the database NormalTracings.TEG in the TEG directory. This database is a collection of normal tracings for the various sample types. You can reselect and save the normals you need, then open the patients database again.]
In Maximized view, to toggle the display of the normal tracing on or off, click on the Normal button in the local toolbar.

The patient sample is displayed in white, while the normal tracing is shown in blue (unless the video setting for these tracings have been changed in the user preferences, in which case, those settings override the defaults).

To turn off the normal tracing, click again on the Normal button in the toolbar. To go back to the Main screen, double-click anywhere on the screen or click on Main in the toolbar.

![Figure 4.22. Click Multi to start selecting multiple tracings](image1)

![Figure 4.23. Click on Done to end selection and display tracings](image2)

You can display both the normal tracing and the reference tracing at the same time. When both tracings are viewed with the patient sample, the patient sample is shown in white, the reference tracing in red, and the normal tracing in blue (again, unless the defaults have been changed in user preferences).

![Normal and Reference tracings together](image3)
**Multiple maximized tracings** To view multiple tracings together, in the Main screen, first click on Multi in the local toolbar.

Notice that the button name changes to Done.

Then click as many tracings as you would like to view together (select from either the tracing panel or from the data panel). You can only select samples with tracings for multiple viewing. As you select a sample, you will notice a cyan blue border in the tracing panel and highlighted numbers in the data panel for selected samples.

![Figure 4.24. Main screen in multiple selection mode](image)

You can scroll up and down the data panel at the right to view and select additional tracings. When you are done selecting, click on the Done button to go
to the maximized view. Note that multiple tracings can only be viewed in maximized view.

Figure 4.25.

The tracings are displayed offset from each other with each tracing in a different color. If you want to view the tracings superimposed on each other, click on the Super button in the local toolbar. The name of the button changes to Offset. You can click to toggle between these two views.

Figure 4.26.
The textual information is color-coded to the tracing color, and you can cycle from one tracing to the next by pressing PageUp and PageDown.

If the data panel is turned off in Multi view, you can activate it by clicking on the Data button in the local toolbar or clicking any tracing. As you move the mouse onto a tracing, the cursor changes to a hand, indicating that you are positioned on the tracing and can click on it.

Note that the identifying information in the top of the data panel is color-coded to the tracing. You can use PageUp and PageDown to cycle through the data panels, click the Previous or Next button, or click on whichever tracing’s data you wish to view.

You can also enable normal and reference tracings while in Multi view by clicking on the desired button. The normal and reference tracings are displayed in their usual blue and red colors, respectively.

Special multi view

Two special views can be displayed using the multiple maximized tracings capability:

- **Functional fibrinogen level.** This is displayed when exactly two samples are selected, one of which has the FF, CFF, FFH, or CFFH sample type, or when FF, FFH, CFF, or CFFH is maximized by itself. The estimated functional fibrinogen level is displayed in the maximized view, along with several other additional parameters. This is discussed further in Appendix C.
PlateletMapping. This is displayed when exactly three samples are selected, one of which is a kaolin sample (plain, citrated, or heparinase), one of which is A(P1) sample type, and either a ADP(P2) or AA(P3) sample type, for measurement of the inhibition of ADP/GPIIb-IIIa or thromboxane A2/GPIIb-IIIa platelet receptors, respectively. Note that this creates a “PlateletMapping cluster” that is stored as part of the case data, and can be viewed or reported using the Case management function described in Chapter 5 under Case Management on page 75.

Hemostasis diagnosis and treatment decisions are sometimes difficult to arrive at. Frequently, published articles contain data that can assist in these processes. The TEG® software provides an option called Guide™ that incorporates examples of various common coagulopathies that are derived from industry publications (see reference list at the end of Chapter 1 on page 15) so that you can compare your patient samples against these conditions. Guide™ provides a step-by-step walkthrough of pattern matching of a selected patient sample against common coagulopathy tracings.

After you select one of the patterns, Guide™ may list other coagulopathies you should consider. You can go back and forth (using the Next and Back buttons) between the Guide™ screens to select another coagulopathy pattern.

To access Guide, select a tracing and then click on the Guide icon in the Main toolbar:

![Guide™](image)

The Guide wizard opens (Figure 4.29) and prompts for bleeding status and whether platelet blocker drugs were administered. Make the appropriate selections.

![Guide wizard - bleeding status](image)
Click Next to continue (or Cancel to abandon the Guide session).

The next screen (Figure 4.30) presents the selected tracing with tracings of common coagulopathies. From this screen, you have two options to perform pattern matching:

- Select a matching tracing (as shown in Figure 4.30) and click Next, or
- Click Show me to display information about the top match.

Although the “Show me” method is quicker, the Selection method offers the advantage of also listing other coagulopathies that cannot be ruled out based on available test data. For example, in the early stages of the tracing, more conditions are listed for consideration, since fewer parameters are available to exclude conditions.

The Show Me option displays the best match, along with other conditions for consideration, if appropriate. The “best match” is derived from both a mathematical/statistical formula and a decision tree. In this example, we selected the lower right tracing, and clicked Next.

![Figure 4.30. Guide wizard - selection for matching](image)

A manual selection that is not the best match will list other conditions, as shown below in Figure 4.31. (If more than one condition is listed, the first is
the condition that would have been shown had you selected “Show me” in the first screen, Figure 4.30)

This screen superimposes the two patterns, displays the coagulopathy for the pattern selected, and, if applicable, suggests other close match conditions that cannot be ruled out, in this instance, surgical bleeding. In this example, we clicked on the suggested coagulopathy, then on Show me. The patient tracing is superimposed with the suggested coagulopathy (Figure 4.32).

Remember that you can go back and forth between these screens to explore the different possibilities. All the clinical information regarding the patient’s condition, the procedure, previous therapy, etc., taken together with the results from the TEG® analyzer and the suggestions from Guide™ will help you make your therapy decision.

See Chapter 5 page 83 if you are interested in adding your own tracings to expand the coagulopathy library in Guide™.
Adding Notes

You can add optional descriptive notes about the sample or patient at any time. The notes text is printed on reports.

Click the Notes icon

Patient notes

To access the Patient Notes screen, select a sample (thereby selecting the patient), then click on the Notes icon in the main toolbar:

Figure 4.33. Click on Notes icon to access notes screen

This opens the Notes screen and lets you view, input, or modify text of any length to describe the patient condition, protocol irregularities, or any other optional text that you wish.

Figure 4.34. Patient notes screen

Click on the Done button in the local toolbar to return to the Main screen.

An "¶" indicator in the Sample description field signals that Patient notes are available to be viewed for a patient.

Figure 4.35. Patient notes flag
The indicator may also be shown in the tracing panel, depending on the length of the patient name and procedure.

![Image of patient notes flag](image)

Figure 4.36. Patient notes flag

The patient notes are printed on all sample and case reports, ahead of sample notes, if any.

To enter notes that are specific to a sample, for example to describe any anomalies in the blood draw, click on the SNotes icon in the local toolbar to bring up the Sample notes screen.

![Image of sample notes screen](image)

Figure 4.37. Display Sample notes screen

Note that this is one of the screens in the set called the “Detail” view, which is described fully in Chapter 5, beginning on page 65.
You can tell which samples have notes by looking at the sample description that is displayed above the tracing or in the sample ID panel. Samples with sample notes display a “$” symbol before the description.

![Notes indicator in sample ID panel](image)

You can view the related notes by clicking on the Notes button in the main toolbar from any screen.

Both patient notes and sample notes can be applied at the same time. They are indicated with both flags, as shown below.

![Patient and sample notes indicators in sample description](image)

The sample notes are printed on all sample and case reports, after any patient notes, if any.

### Printing Reports

Single sample reports or multi-sample reports are printed depending on the number of samples selected and the choices made in the Report options dialog box that appears after clicking the Report button in the Main screen.

You can print two types of blood sample reports or listings of patient IDs and names at any time.
The blood sample reports available are:

- Quick print of maximized view
- Detailed sample report with CPT codes for billing with numerous options for customizing output.

In addition, a "case summary" report can be generated that provides an overview of the progress of a case. The case summary report is described in the next chapter.

Report headers are customized by the Site Administrator to include information about the site running the tests, as appropriate.

To generate an instant report, with no prompts, to be sent to the default printer, press F6. The format of the output is described below under “Quick print.” The only difference between the two is that Quick print lets you select a different printer, and prompts you for additional information.

Quick report prints the contents of the maximized screen for a sample, whether you are in maximized view or not. To print a quick report of one sample, follow these steps:

- In the Main screen, select one sample for which you want to print a tracing or press F6 on the keyboard, or
- In Maximized view when a single sample is displayed

Select Print from the toolbar:

![Print icon]

*Figure 4.42. Click on Print icon to invoke Quick Print*

This option automatically displays maximized view if you are not already in maximized view, and presents the standard Windows Print dialog box that lets you select a printer and set the number of copies you would like to print. This
print dialog differs among the different versions of Windows, so what you see may not exactly match the screen shown here (for Windows 2000).

If you wish to print using the default settings, just click on Print or OK, whichever option is presented in your version of Windows. Otherwise make the proper selections before clicking OK or Print. Click Cancel to abandon the printing.

Note that Quick print only produces output for a single tracing. To obtain a similar report for multiple tracings, use the Report option as described below after selecting the multiple tracings.

Full report

Select the sample

Click on Report

To print a full report of one or more samples, follow these steps:

In the Main screen, select the sample for which you want to print a report. If you are in Maximzed view, all tracings displayed are automatically selected.

Select Report from the toolbar:
A report dialog box prompts you for additional options:

By default, both the tracing and numerical data are printed on the report. You can also select Clot to print the clot graphic when reporting on a single sample. Inclusion of the PlateletMapping pop up box data on the multi-sample report is optional. The Site Administrator determines the setting.

If you have multiple tracings selected, by default the output for the tracings are color-coded to the numeric data. You can override this default for black and white printers (such as lasers) by clicking Print text in black under Graphics options. Using that option, text will not be printed grayscale to mimic color, but will, instead, be printed in black.

If you have one tracing selected, a default report formatted for patient recordkeeping is produced, with the option of printing the default first ten tests or all tests. Click Continue to go to the Print preview screen.

Using the Report option, you can print all the samples in the database or only selected samples.

Note that following the All option, the number of samples in the database is shown in parentheses. Following the Selected sample(s) option is the number of samples selected for printing. If you are clicked on one tracing, the number is 1; if you have selected multiple tracings, the number of tracings selected is displayed. The maximum number of tracings you can print at a time is 50. (If you are not printing the tracing, only printing the numeric data [i.e., Tracing is not selected], there is no limit to how many samples can be printed. In this instance, the report will contain a tabular listing of the numeric data for the samples listed.)
Once you have specified what you want to print, the report is presented in Print preview mode.

If you are satisfied with the preview, click on the Print button to print the report. Note that the Print dialog box that is presented when you select Print also lets you select which pages to print. You have the option of all pages, a specific page, or a page range. To close preview mode after/without printing, click on the Done button.

**CPT codes**

CPT codes for reimbursement purposes are listed at the bottom of the full report for a single sample (they are not listed in multi-sample reports). Note that CPT codes are listed only when a parameter is finalized. No code is listed for interim values.

This option is controlled by the Site Administrator, and can be turned off if your site does not use these CPT codes.

**Patient summary**

You can easily print a chronological patient summary report by first filtering for the patient name (Patient filter on local toolbar), then clicking on Report in the main toolbar. When the report options dialog box (figure 4.45) is displayed, choose All samples under the Sample options heading to produce the report. The report displays the tracings in chronological order top to bottom, followed by the numeric data in the same order. If you are printing to a color printer, the numeric data is color-coded to the tracing color.

**Patient listings**

To print a listing of patient IDs and names, follow these steps:
In the Main menu, select Records, then Patient report.

![Figure 4.47. Patient report option](image1)

The patient report presents two sorting options:

- Sort by patient name
- Sort by patient ID

When you have selected one of these options, you can then specify whether the sorting should be ascending or descending, and click on Done.

The report is presented in Print preview mode as described above for the full report. To print or cancel the report, click on either Print or Done, respectively.

Single and multiple tracings can be electronically copied and pasted into other documents. Select the desired tracing or tracings and click the Capture button. The Capture options dialog box appears. Choose the format options and click the OK button. Paste the capture into a document.

![Figure 4.48. Sorting options](image2)

![Figure 4.49. Capture options dialog box](image3)
Undo

An Undo icon is provided in the Main toolbar and in selected screens throughout the software. Clicking on Undo reverses only the last edit performed, and only until you leave the screen in which the edit was done.

Help

To access help and information about the software, select Help and a drop down menu appears.

- Select Help Topics for the Operator’s Guide.
- Select Test Description for a list of tests with descriptions.
- Select Haemoscope on the Web to reach Haemoscope’s web site. An internet connection is required.
- Select About TEG® software for the software version number and database version.

Exiting the Program

To exit the program, first select File in the Main menu, then Exit.
Chapter 5

More Views of TEG® Data

Audience: Clinicians, TEG® operators, researchers

This chapter describes additional options available for viewing and using TEG® data, including using the screens available in Detail view, using advanced, user-defined filters, and using TEG® tracings with other software. This chapter also describes the use of the case summary report.

The sample detail view is really a collection of three screens:

- Tracing detail
- Notes detail
- Sample detail

Each of these screens is accessed through the tabs as shown below in figure 5.1.

You can access sample detail information by clicking on the Detail button in the local toolbar or on the Status bar (see page 68.)

If you access the Detail view by clicking the icon, the Tracing tab is displayed (as in figure 5.1 below). If you accessed the Detail view from the status bar, the appropriate tab containing that data is displayed.

To return to the Main screen, click on the Main button at the end of the local toolbar (shown in figure 5.1 below).

Double-clicking the tracing takes you to Maximized view.
Tracing Detail

The tracing detail screen summarizes all the numerical data for the selected sample, while showing the tracing at the left. From this tracing detail screen, you can access and enter additional sample data that is not collected by the TEG® analyzer, such as aPTT or RBC. (Notice that the tests that appear here, as well as the order in which they are shown, is controlled by your user profile, and can be changed as described in Chapter 9.)

View clot

You can turn on the clot graphic in Detail view by clicking on the Data icon in the local toolbar. (If the clot graphic is not displayed, click on the Clot icon to bring up the clot. If the clot icon is disabled, the clot graphic is not available at your site.) Clicking the Data icon again clears the Data panel.

Enter other test data

You can enter data for other tests that relate to this sample by clicking in the left cell of the blank line at the bottom of the data table (as shown above in figure 5.1 and figure 5.2 below). Select the test name from the pulldown
menu. (Note that if many tests are already stored, the pulldown menu is displayed above the line you choose instead of below.)

![Figure 5.2. Entry of related data](image)

Then move to the Value cell to enter a numeric value. You can only enter data for non-TEG tests (unless it is a manually created record, as described in Chapter 6). You can only modify data you have entered. You cannot enter data for tests that are not in the list and you cannot change values for any of the data calculated by the TEG® analyzer. The table below summarizes:

<table>
<thead>
<tr>
<th></th>
<th>TEG-run sample</th>
<th>Manual record</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEG tests - enter</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>TEG tests - change</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Other tests - enter</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Other tests - change</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

You can set a tracing to be a temporary reference (baseline) against which to compare other tracings for this patient, as well as to be the “normal” tracing for the current sample type, as described beginning on page 47.

The sample tab provides for entry of optional reported interpretation text describing the TEG® tracing, as well as entering who ordered the test, and who the surgeons and anesthesiologists are. For your convenience, the main TEG® clot formation and lysis parameters as described in Chapter 1 are presented above the reported interpretation field for reference. All this information is for...
your convenience and is optional, so if your site does not require/want this information on reports, you need not enter it.

Notes Detail

The sample description field described earlier in Chapter 4 may not be sufficient to describe a sample or patient condition. In that case, additional patient notes can be entered by way of the Notes tab and sample notes can be entered by way of the SNotes tab, as described earlier in Chapter 4.

The sample Notes tab can also be invoked directly from the Main screen by clicking on a sample and then on the SNotes icon in the local toolbar.

The Status Bar

The status bar at the bottom of the Main screen, just above the Windows taskbar, provides additional information about the sample and your environment. To the right of the message “Double click tracing to maximize,” the following information is listed for the selected channel (left to right):

- Number of records available for viewing / number of records selected in multi-tracing mode (9)
- User name (jonas)
- Patient ID (H53425357)
- Site ID (HAEMOSCOPE)
- Operator ID (NMS)
- Date of sample (10.28.1998)
- Time sample started (09:01:07 AM)
- *TEG® column temperature (37°C)

* You can edit this data by clicking in the status bar.

(If you click on the Patient ID field in the status bar, the Edit case screen is displayed and any patient information can be edited, as described below in the section named "Case Management.")

After editing the sample information, return to the Main screen by clicking on the Main button in the local toolbar, as shown earlier in figure 5.35 on page 56.

An earlier section described how to suppress unwanted records by patient, site ID, and/or active status. This section shows how to specify your own criteria to filter out records you don't wish to view.

To filter on a broad set of criteria including:

- Ranges of values for test results
- Patient name or Patient ID
- Sample type
- Channel number
- Date ranges

Figure 5.5. Click on Filter to invoke advanced filtering

To filter on these criteria, click on Filter in the local toolbar.
The filter criteria dialog is presented:

![Filter criteria dialog]

**Figure 5.6. Filter criteria specification**

Each different type of filter is presented on its own tab. Click on any tab to enter criteria for that tab. The criteria are cumulative, so that all the tabs in combination are used to filter the data.

For test results and other data, select a data item and then specify either one value in the first box or a range in both boxes, as appropriate. For example, select R and enter 320 to display only samples with R of 320, or select R and enter 200 in the first box and 320 in the second box to display samples with R between 200 and 320. You can select more than one test (by clicking on More and entering another set of criteria) and combine it with other specifications such as patient name, date ranges, or sample type. When specifying ranges for tests, the values you enter here use whatever units you have specified in your user profile.

To specify a patient for filtering, either select a patient from the local toolbar in the Main screen before you enter this screen, or select either a patient name or ID in the filter screen.

For dates, enter either one date in the first box or dates in both boxes to specify a range; for example, 01/20/1999 to retrieve all records for January 20, 1999 or 01/20/1999 in the first box and 01/01/2000 to retrieve all records between the two dates, inclusive.

You can select any combination of these fields, to a maximum of 40 different criteria.

The Custom tab lets you filter on any other field contained in the patient data-
base. For example, to search for a specific accession number, select that field from the pulldown and enter the criteria in the boxes to the right.

Click on Apply filter to perform the filtering after specifying your criteria. The Main screen is displayed and contains only the records, if any, that meet your criteria. If no records match your criteria, a message is issued to that effect.

If you want to clear all your criteria and enter new ones, click Clear all. To abandon the filter operation, click Cancel.

To clear the selection filter, click on Filter on the local toolbar.

Remember that these results are used in combination with the Active filter and with the Site ID filter. So, you could view all samples for Linda Rabinowitz, or only active samples for Linda Rabinowitz, or only active samples for Linda Rabinowitz sent from OR2 on a given date.

The virtual subset you create using either the quick filters, the user-specified filter, or combination, is used not only for viewing samples, but also when exporting data, as described in Chapter 7.

As mentioned earlier in this manual, TAS supports the management of "case" data, so that it is possible to generate summaries of cases and to isolate one procedure from another for a given patient.

Cases are created usually by the operator at the time the first sample is run. By clicking on the Case icon in the Main toolbar, the options for adding a new case or editing an existing case are presented.
Case management presents options for managing data related to:

- Procedures
- Therapy
- Blood products administered
- Patient (case) notes
- Miscellaneous demographic information
- Data locking
- Clinicians
- Platelet mapping cluster data
- Samples

This information can be entered at any time, either contemporaneously or after the case is completed, except for case identifying data. (While at first glance it might appear cumbersome to enter such data, remember that the more data entered here, the more meaningful the case summary report will be.) Except for Patient ID, name, and procedure name all other information is optional, and is output only on the case summary report and any exported file to spreadsheet and statistical software.

**Procedure**

The procedure tab provides for entering general information about the case. In addition to the procedure name, and optional description, you can enter
information about times, interventions -- including types and times, patient output -- including type and volumes, and patient outcome.

The Rx tab provides a space for entering any drugs used before, during, or after the procedure.

By inputting the values here with times, the case summary report trends will indicate these values on the timeline when displaying the test trend as well as in the numerical grid (see below under Case summary report). Note that you have the option to total here by drug.
Blood products

The administration of blood products can be tracked through the Blood products tab.

**Figure 5.12. Case Blood products tab**

Similar to the Rx tab, it allows entry of type, amount, and date of blood product administered, and, if entered here, will be incorporated into the numeric and graphical trends in the case summary report.

Notes

The patient/case notes tab provides for entry of descriptive notes that can be edited (added to) during the course of the case, or can be entered after the fact.

**Figure 5.13. Case notes tab**

These notes are printed in the case summary report, as well as in the single sample report. If sample notes are also entered, as described in Chapter 4, then they follow the case notes.
The Other tab lets you enter social security number (SSN) and birthdate, if desired. Note that the birthdate does not affect the entry of the age field in the upper part of the screen. It is not used to calculate the age that is manually entered there.

The Locking tab provides a means to lock out unintentional editing of data on completed cases for whom the data has been reviewed.

It is to be a safeguard, not a security feature, and can be unlocked at any time to make corrections, if needed.

The Clinicians tab allows entry of any clinicians involved in the case.

The Clusters tab automatically collects data for any sample clusters that are created by the software for PlateletMapping (see Chapter 4, page 53). Whenever a calculation for PlateletMapping is displayed either for ADP or Arachidonic Acid, TAS creates a data "cluster" so that the samples included in the platelet inhibition calculation are identified and can be recalled for report-
ing or viewing. (Note that deleting a sample that belongs to a cluster also deletes the cluster and the resultant percent inhibition calculation.)

Figure 5.16. Case cluster tab

Samples

The Samples tab provides a summary of the samples analyzed for a patient, and lists the bleeding status, temperature, and whether the patient is taking platelet inhibiting drugs.

Figure 5.17. Case samples tab

To change any information listed in the samples tab, select a row and click on Edit. The Sample detail screen described earlier in this chapter is presented for editing this data. Click on Case in the local toolbar to return to the Case samples tab.

Case summary report

The case summary report is accessed from the Case screen by clicking on Report.
A report options wizard walks you through the needed information to generate the case summary report. It begins by asking which samples should be included in the Report. Click on all of the samples you wish to report.

When generating a case summary report, you may wish to choose representative samples at critical protocol timepoints for display. The trend lines are generally more useful when the same sample type is selected so that the points are connected and the samples truly represent the progress of the patient's procedure.

The next screen prompts you to select which tests to display on the report, followed by information on the size of the graph, and details about the tracing display. To select tests, click on a test name in the left column, then on the > arrow. To deselect, click a test in the right column, then on the < arrow. You can move all tests in either direction (typically not desirable), by using the
and << arrow keys. The other settings' default values are usually suitable.

The report consists of three main parts:

- Numerical data summary
- Trend graphs
- TEG tracings

The numerical data summary presents the data from the various tabs in the
Case group: patient and procedure information, interventions, notes, TEG® test numerical results, etc. An excerpt on this section is shown here:

**Patient**
- **Name:** Johnson, Gene
- **Gender:** m
- **Age:** 57
- **Weight (kg):** 47

**Procedure**
- **Name:** Marfan/M repair
- **Surgeon:** Dr. Surgeon
- **Anesthesiologist:** Dr. Anesthesiologist
- **Pathologist:** Dr. Pathologist
- **Hematologist:** Dr. Hematologist
- **Perfusionist:** Dr. Perfusionist

**Rx**
- **Drug:** Sample drug
- **Amount:** 43.00
- **Units:** IU
- **Total:**
- **Date:** 7/18/2001 2:14:00 PM

**Coagulation Profile**

<table>
<thead>
<tr>
<th>Test</th>
<th>Baseline</th>
<th>on pump</th>
<th>Rewarming</th>
<th>PP / after 12 units of platelets</th>
<th>ICU / after 6 units of platelets</th>
</tr>
</thead>
<tbody>
<tr>
<td>R (min)</td>
<td>3.53</td>
<td>7.15</td>
<td>7.72</td>
<td>20.90</td>
<td>9.06</td>
</tr>
<tr>
<td>Angle (deg)</td>
<td>54.50</td>
<td>29.50</td>
<td>26.50</td>
<td>60.00</td>
<td>72.00</td>
</tr>
<tr>
<td>MAP (mm)</td>
<td>44.00</td>
<td>25.00</td>
<td>22.00</td>
<td>57.00</td>
<td>64.00</td>
</tr>
<tr>
<td>G (G/sec)</td>
<td>3.93K</td>
<td>1.67K</td>
<td>1.44K</td>
<td>6.83K</td>
<td>0.89K</td>
</tr>
</tbody>
</table>

Figure 5.21. Case summary report - excerpt of numerical data

The trend graphs show you the trend for each selected test, along with relevant therapy and blood product administration during the time period selected by the samples. This section of the report is preceded by a legend that lists the sample descriptions and therapy/blood product use.

**Trend graphs**

**Trends**

1. Baseline
2. on pump
3. Rewarming
4. PP / after 12 units of platelets
5. ICU / after 6 units of platelets

**A:** Sample drug 43 IU
**B:** Platelets 6 IU
**C:** Platelets 12 IU

Figure 5.22. Case summary report - trend graph legend
This is followed by the trend graphs for the selected tests.

![Trend graphs for selected tests](image)

Figure 5.23. Case summary report - trend graphs for selected tests

Note that if you did not select samples of the same sample type, only the points that belong to the same sample type are connected with a line. The sample type for each sample is listed next to its point. This can be significant when, for example, you have selected some samples that are heparinase-treated, and some samples that are not heparinase-treated.
The individual tracings for the samples you selected are next. These are displayed in a smaller size, to allow for up to six tracings to fit on a page.

![TEG tracings]

Figure 5.24. Case summary report - individual TEG tracings for selected samples

You can print the entire report or selected pages. When you click on the Print button, a dialog box is presented within which are options for printing page ranges. By default all pages are printed.

![Page Range]

Figure 5.25. Print -- page range option.

A copy of the currently selected tracing(s) can be copied as an image to the

Using TEG® Tracings with Other Software
Windows clipboard for use in other programs simply by clicking on Capture on the Main toolbar.

![Main toolbar with Capture option](image)

*Figure 5.26. Click Capture to copy the tracing(s) to the clipboard*

You are prompted for additional options.

![Capture options dialog](image)

*Figure 5.27. Capture options*

Select Results if you wish the numeric data to be captured along with the tracing. Select No results if you want only the tracing.

Select either Black or White background. Black background is useful when the captured tracing will be used on a 35-mm slide or in an online slide presentation such as PowerPoint. A white background is useful when the tracing will be used on overhead transparencies or pasted into a word processing document.

Click OK when you have set the options you prefer. Then, open the destination software (e.g., Microsoft Powerpoint, Microsoft Word, Harvard Graphics, etc.), position the cursor where you want to place the image, then from the main menu select Edit, then Paste, or press Ctrl+V.

You can repeat this procedure for additional tracings. Only one captured image can be held on the clipboard at a time. The image can contain a single tracing or can contain an image of Multi view with multiple tracings.

Remember that the tracing is only a graphical image when it is transferred to another software package in this manner, and you cannot manipulate either the tracing or the numbers, except to place the tracing or resize it.
The six most commonly encountered coagulopathies are presented first in the Guide™ selection window. You can expand the library of tracings presented in the program to include tracings of your own.

Note, however, that the tracings you add are for visual comparison only, and cannot provide the same type of statistical/algorithmic evaluation as the standard library tracings. In other words, you can select the new library tracings and overlay them onto patient tracings. The information for coagulopathy and suggested treatment will be presented for consideration, but none of the new tracings will appear in the Pattern matching screen in the box under alternate coagulopathies. The only recommendations appearing in that box are the original ones distributed as part of the TEG® software.

In addition to adding new tracings to the library, you can also modify information about any tracings you have entered, as well as delete unneeded or obsolete tracings you have entered. You cannot modify or delete the original system tracings.

To add a tracing to the library, it must be selected and be the current sample in Guide™. In the Selection window of Guide™, click on Add in the Library frame in the lower left corner.

![Guide screen with Library frame](image)

**Figure 5.28. Guide screen with Library frame**

The Add to Guide screen provides for entering the description of the
coagulopathy, the common treatment, and any descriptive comment to display on the screen when this coagulopathy has been superimposed.

You can also select bleeding status and therapy administered conditions that are appropriate for that new condition. If the category does not apply, click Ignore. When the coagulopathy is selected in Guide™, if the bleeding status or therapy administered conditions do not match, a message is listed in the Pattern matching window under the superimposed tracings.

The next screen shows the Therapy consideration window with the newly-de-

Figure 5.29. Adding an entry to library

Figure 5.30. Your entries in use in Guide™
fined coagulopathy entries. Note the text at the top of the window identifying it as a member of the user-defined library.

![Guide - Therapy consideration window](image)

**Figure 5.31. Your entries in use for therapy consideration**

To modify a library entry, you must be in the Guide wizard. You can select any tracing in the database (e.g., in the Main screen), then click Guide™, as usual. Once in the Guide wizard Pattern selections window, select the tracing from the panel at the right, then click on Modify in the Library frame at the bottom of the window.

![Guide - Pattern selection window](image)

**Figure 5.32. Select Modify to change an entry**

Make any required changes in the Add to Guide screen (Figure 5.29), then click Save to store the modifications you have made, or Cancel to abandon the changes.

To delete a library entry, follow the steps outlined above for Modify a library entry, except select Delete instead of Modify in the Library frame. You will be asked to confirm the deletion.
This section describes the functions available from the “Records” option on the Main menu, namely:

- Create patient
- Create record
- Delete patient
- Delete sample

along with an alternate way to create a new case/patient.

Note that these options are not available if you are logged in with Guest user group privileges. Check with your site administrator.

If you want to create a patient for whom you will be running blood samples, click on the Case icon in the Main toolbar. You can define patients even if you will not be running samples for them in this session.

Note that if you omit this step, you will automatically be sent to the Case definition screen when you try to enter a new patient from the TEG screen when you are running samples.

A dialog box asking if you are creating a new case or editing an existing one is
presented. Select Add case. The Create case screen is displayed and asks for some cursory information.

![Create case screen](image)

**Figure 6.2. Create case screen**

Patient ID and patient name are required; the remaining fields are optional. Additional optional information can be entered at another time by splicing on the Case icon as shown in Figure 6.1, and selecting Edit case.

### Creating a record

If you want to create a record to contain manually entered data, click on Records in the Main menu, then New, then on Record.

![New record creation option](image)

**Figure 6.3. New record creation option**

You are prompted to select a patient and after clicking Continue are taken to the Tracing tab of the Detail screen as described earlier on page 66.

### Deleting patients

To delete a patient, click on Records in the Main menu, then Delete, then on Patients. (Note that this option may be disabled at your site by the Site Administrator.)

![Delete patient option](image)

**Figure 6.4. Delete patient option**
This presents the Delete patient dialog:

Click on a patient to select, then Delete to delete a patient. Repeat this process to delete additional patients.

Use caution when performing this operation! All records related to this patient, including all samples, notes, etc., are deleted along with the patient record. If you delete a case, only the most recent deletion can be restored, and only before leaving the screen.

To delete specific records for a patient, select Records > Delete > Samples from the Main menu. (Note that this option may be disabled at your site by the Site Administrator.)

You are presented with the Delete samples screen.

Click to select a record for deletion, then on Delete to complete the deletion. Repeat this process to delete additional samples.

Use caution when deleting samples. If you delete multiple samples, only the most recent deletion can be restored, and only before leaving the screen.
Database operations

**Audience: Site/Database administrators, researchers**

In the course of operations, several database operations become necessary. You may wish to create a new database for specialized samples, to import data from older versions of the TEG® software, to export data, etc. This chapter describes these operations.

You can change to another database during a TEG® session by selecting Open database from the File option on the Main menu.

![Figure 7.1. Open Database option](image)

*Figure 7.1. Open Database option*
The Open file dialog box is presented. Navigate to the directory your database is in, if needed, then select the database name to open.

Your currently opened database is closed before opening the one you requested. If you have active samples, you are prompted to end them first. QC samples are copied, if any exist, providing the option is set in the User Profile to transfer samples.

Creating a new database

To create a new database, click on File in the Main menu, then select New database.

Figure 7.2. Database selection for opening

Figure 7.3. New Database option
You are presented with a dialog box that prompts for the type of database to create. If you are running the Remote version, the QC prompt is disabled:

![New database type selection](image)

Figure 7.4. New database type selection

Once you have chosen a database type, you are asked to name the new database:

![New database name specification](image)

Figure 7.5. New database name specification

Type in the name for the new database in the File name field (without the .TEG extension), then click Open. When the database creation is complete, you are asked whether the new database you have just created should be set as the default for this user. The database you have just created now becomes the current database, and is empty until you create a patient and run samples or import/merge other databases.

Your currently opened database is closed before opening the new one.

If you are using a database that is very active with samples being saved day after day, or if you have imported or merged other databases, your database may become unnecessarily large due to the way the underlying database system manages the storing of data. (Note that there is no practical limit on the number of samples you can store in a database. However, if you approach the maximum size limit of 2GB, the database will stop working; the software will give a warning before the 2GB maximum is reached. You may also notice that
your system is taking longer and longer to retrieve data. For these reasons, you may wish to compact the database to improve performance.

To compress the amount of space the database takes on your hard drive, use the Compact database utility.

To protect the database in the event samples are running or other users are modifying data, you cannot compact a database that is open, even if you are the only one using the database. If you try to do that, the system issues a message that the database is busy and cancels the compacting process.

We strongly recommend making a backup copy of the database using Explorer or My Computer before running Compact database.

From the File menu, select Compact database.

![Compact database option](Figure 7.6. Compact database option)

Then select the name of the database to compact (not the current database).

![Database selection for compacting](Figure 7.7. Database selection for compacting)
You can merge other version 4 TEG databases into the database you are using by using the Merge option. Do not merge databases that contain active samples either in the source or target database.

Before you begin to merge, first make sure that you are in the database into which you want to import the V4 database(s). Create a new database, if needed, or open the destination database, then select Merge from the File option on the Main menu.

The Merge file dialog box is presented. Navigate to the folder your database is in, if needed, then select the database name to copy into this database.

The records from the specified database are copied into your current database, with duplicates deleted. Duplicates are considered to be samples where patient id, sample date, sample time, sample type, and channel number match.

If the incoming database contains user-defined tests not created in the current database, you are prompted whether each additional test should be added or skipped. If you select skipped, the additional tests from the incoming database are ignored.

The other database is left intact, since a copy is merged.
Importing V2 databases

You can import existing version 2 TEG® databases into your version 4 database. First make sure that you are in the database into which you want to import the V2 database(s). Create a new database, if needed, or open the target database to receive the version 2 data.

Select Import, then V2 Database from the File option on the Main menu.

The import dialog box appears.

Select the drive and folder that contain your version 2 database(s). Select one or more databases, then click on Import to begin the conversion and import. (To select multiple databases, hold down the Ctrl button while you click on database names.)

A running counter of how many tracings are being imported appears at the bottom of the window. If duplicate samples are created as a result of importing into the database, they are automatically deleted at the end of the import, and a message tells you how many duplicates were deleted. Duplicate samples are those that have the same sample identifying information, i.e., patient id, sample type, channel number, date and time. If any sample are missing patient names and id’s, the date and time of import are inserted into those fields. The V2 database remains intact, since a copy is imported into version 4.
In some instances, version 2 databases may not have associated “.PX” files. (See the Version 2 manual for an explanation of the files that comprise a database.) If this is the case, the import to version 4 will fail and an error message will be issued. To overcome this problem, you need to perform a “fixit” operation to reproduce the “.PX” files as follows:

☐ In version 2, create a new database.

☐ Using the Merge operation from the main menu, merge FROM the old database TO the new database.

You can then proceed to import the new database into version 4.

Version 2 databases contain several sample types that receive special handling in version 4:

☐ Heparinase: Although this sample type is imported from version 2 databases, it is not available for selection in v4.

☐ ReoPro: This sample type was renamed in version 3 to FF—Functional Fibrinogen Level, to reflect that this sample type displays a value for functional fibrinogen level in the maximized screen.

Special 1 and Special 2 sample types have been retained if they exist and are imported as is into version 4.

The conversion process for importing version 1 data files into a version 4 database follows exactly the same process as outlined above for importing version 2 databases. Select File, then Import, then V1 data file from the main menu.

The file selection window is displayed. Select your file or files, then click Open. Note that to select more than one file, you have to press and hold the Ctrl button while selecting. The progress counter, as described above for V2 imports, is displayed, and duplicate handling is the same as for V2.

Even though the data formats are different between version 3 and version 4 databases, version 3 databases can be imported into version 4 databases simply by selecting Merge from the File menu and selecting the database name.
The version 3 database is backed up and then converted to version 4 format and merged into the version 4 database.

**Exporting TEG® data**

TEG® data can be exported in one of two formats:

- Native TEG® database format, which allows you to take an entire database or a subset of a database and create another database from it.

- Tab delimited, which is appropriate for importing into Excel, various databases, or any other program that accepts tab-delimited data. As part of this option, you can also export the tracing coordinates to a file that can be used to plot the points in another software package.

You can export all the data in the database, or select one or more tracings to export.

Select Export from the File option on the Main menu:

![Figure 7.13. Export option](image)

Select the appropriate sample option, then click Next.

![Figure 7.14. Export sample data selection](image)

Select the type of export you want to perform along with any of the supple-
mentary files (if tab delimited is selected), then click Next. If you do not select any of the supplemental file types, only the tab delimited data file is created.

![Export data wizard](image)

Figure 7.15. Export format selection

If you select the Subset option, by default the subset, if any, you created with the Filters feature will be exported. If you pick the Subset option and check the “Let me pick samples” check box, you are further prompted to select samples for export (regardless of any subset chosen through the Filters option):

![Sample selection](image)

Figure 7.16. Export sample selection

To select a sample, click anywhere in the row.

To select additional samples, hold down the Ctrl key while you click each additional sample. When you are finished selecting, click OK.

The next screen asks for the type of export file to prepare, as shown earlier in Figure 7.15.

The final screen prompts for the filename for the export file. Type the filename for your export file into the File name field, then click Save. The software automatically appends the TXT extension to the file name you specify. If
you selected to export the coordinates, they reside in the file you specified, with the extension CRD.

See the next chapter named “Using Export Files” for information on how to import these files into other software packages and for further information about the structure of the export files.

A special form of export is available for consultations with colleagues and specialists. eConsult creates export data, bundles it with user-entered clinical and contact information, and sends it via e-mail. Note that a working e-mail client must be installed and operational on the computer being used, since TAS does not provide the e-mail capability, but uses the default TAPI-compliant client that is available.

The eConsult message can be sent to e-mail recipients using various devices, including standard PCs, notebook computers equipped with wired or wireless connectivity, and even personal digital assistant (PDA) devices that are capable of receiving and displaying e-mail with graphical attachments. The graphical attachment sent is formatted to fit the screen of most PDAs.

To start the eConsult wizard, click on the eConsult icon in the Main toolbar.

The following sequence of screens represent the eConsult wizard that walks you through sending the data. The first screen presented asks you to select a patient and, for privacy purposes, asks that you assign a code to identify the patient. Patient identification information is suppressed in the e-mail, and the
code is used to identify the patient. You need to communicate this code / patient information to the e-mail recipient, otherwise they will not know who the patient is. Click Next to continue.

Note that the information you enter in these screens is available for the next eConsult message you send in this session. This information is not retained between sessions.

**Introduction**

The following steps will prepare the data needed to obtain a consultation through eConsult.

**Select patient:**

- **John Doe:** Please select or create a patient
- **Wilson, Jane:** H45678

The software does not transmit patient identifying information such as name, etc. Please type in a code for reference purposes:

DR12CAB6

*Figure 7.19. Patient selection*

A list of samples for the selected patient are presented. Click on one or hold the Ctrl key down while you click on multiple samples. Click Next to continue.

*Figure 7.20. Sample selection*

A clinical data and contact form is shown. Here you may fill in the demographic information, procedure information, therapies (with doses), bleeding
status, and optional comments. Contact information is helpful, as is any lab information. Click Next to continue.

![Image of eConsult wizard (2)](image)

**Figure 7.21. Clinical and contact form**

Two formats for data are available. Samples with tracings sends the numeric and tracing data for the selected samples. The database option sends the selected tracings in TEG database format, so that they can be merged and manipulated by the recipient.

Some tracings are long, up to three hours, and may not contain meaningful information after the first 90 minutes. To save on file size, you can limit how much of the tracing(s) to send. Click Next to continue.

![Image of eConsult wizard (3)](image)

**Figure 7.22. Type of attachment**

Finally, select the recipient for the e-mail message. The message is sent to the selected recipient, and, if one has been entered, the cell or pager number listed will receive a short text message alerting to the presence of the eConsult
e-mail. Note that if a pager is used, the pager must be capable of receiving text (SMS) messages.

<table>
<thead>
<tr>
<th>eConsult setup</th>
<th>(4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Select who should receive your request:</td>
<td></td>
</tr>
<tr>
<td>Consultant</td>
<td>Organization</td>
</tr>
<tr>
<td>Dr. Mayne</td>
<td>Christie Assoc Ltd</td>
</tr>
</tbody>
</table>

Figure 7.23. Recipient selection.

A confirming message is displayed if the send was successful, or, if not, you are asked if the system should try again in 15 seconds.

Access the eConsult setup through the Options menu, User profile setup, eConsult tab. The eConsult feature requires information about your e-mail account (e-mail address and password) to log into your e-mail account and send e-mail. You can choose to store your password so you do not have to enter it each time, or you can select to enter it manually each time.

The bottom of the setup screen lets you enter the recipients of eConsult messages. If no recipients are defined, a message is issued when you click on the eConsult icon in the Main toolbar.

POP3 authentication with the SMTP server is optional. The Site Administrator can change the setting.

If you are operating in a network environment, your databases may be backed up automatically by your site’s computer services staff. However, even if this is the case, we **strongly recommend** you back up your own data. The following table identifies files you should copy to another media or location for backup:

---

**Defining eConsult options**

**Backing Up TEG® Data**
### Table: File Locations and Contents

<table>
<thead>
<tr>
<th>Name of file</th>
<th>Hard drive location</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anything.TEG</td>
<td>User specified directory (default is C:\TEG)</td>
<td>Patient databases</td>
</tr>
<tr>
<td>Anything.QC</td>
<td>User specified directory (default is C:\TEG)</td>
<td>Quality control databases</td>
</tr>
<tr>
<td>CFG.SET</td>
<td>Program directory (usually C:\Program Files\TEGV4)</td>
<td>System and user configuration file</td>
</tr>
<tr>
<td>GUIDE.LIB</td>
<td>Program directory (usually C:\Program Files\TEGV4)</td>
<td>Coagulopathy library</td>
</tr>
</tbody>
</table>

Note that you should replace “anything” in the above list with the name of your file.

You can use standard Windows copy procedures to copy from one location to another or to certain other media, e.g., CD ROM or Zip™ media (depending on your version of Windows). If you wish to copy your files to magnetic tape, you will need to use third party software for backing up.
This chapter describes the use of external (export) files from the databases created by the TEG® Analytical Software. You can export either a single patient tracing and data or multiple patient tracings and data. The exported data provides enhanced reporting and analytical capabilities when used in systems designed for such purposes.

The steps to produce the export output files are documented in the chapter named “Database Operations.”

Two types of files can be created:

- Tab-delimited data files that can be used by spreadsheet packages such as MS Excel® and can be imported into other database packages such as MS Access® or statistical packages such as SAS® and SPSS®

- TEG®-format files that can be used as standalone databases, or can be merged into other version 4 TEG® databases.

Using this approach, you can easily move data out of the daily databases you use in analyzing blood samples and into other software packages for customized reports and/or statistical analysis for CLIA compliance or research purposes.

This chapter shows you how to import the data into the most popular spreadsheet and database software: Microsoft Excel and Microsoft Access. Because of the profusion of other analytical and graphical programs available, it is not possible to document how to import data into all programs. If the software you wish to use has an import option, it can probably read tab-delimited files, and the documentation or online help for your software can help you read the files produced by TAS™.

We assume that once you have imported these external files into another system that you have either the proficiency in the other system or someone available to help you use the other software, since this is not a tutorial in Excel, Access or any other system.
Creating the export file

Follow the instructions given in the chapter named “Database Operations” to create the necessary export file.

Importing into Excel

Generate a file selecting the Excel format option as just described, then start Excel, and follow these steps to import your data:

1. On the Main Menu, click on File, then on Open.

   Select the proper directory.

   In the Files of Type box select All Files, then select your file.

   Click Open.

   ![Figure 8.1. File selection]

2. The next screen (Figure 8.2) asks you to specify whether the file is delim-
3. The next screen (Figure 8.3) asks you to specify the delimiter type. Select Tab. You will see a sample display showing how the columns are assigned. Click Next or Finish. If you click Next, you can set the data formats for each column and/or exclude columns. If you click Finish, the import completes with default data types and all columns. Unless you have special formatting requirements, this is adequate, and you can skip the rest of the steps listed below.

Figure 8.2. Data type selection

Figure 8.3. Delimiter selection
4. If you choose to continue with the formatting options available, the next screen (Figure 8.4) lets you set the data format for each column. You can go through column by column and set data types for each column by clicking on the column name, then selecting the appropriate type from the list at the top right. Click Finish.

![Figure 8.4. Data formatting](image)

Your data is imported and ready for use.

---

**Importing into Access**

Generate a file selecting the Excel format option as described earlier in the section named “Creating the export file.”

1. Start Access, and follow these steps to import your data (Note that some of the prompts may vary, depending on which version of Access you are using):

2. When Access opens, an Opening dialog may appear that asks whether to open a new or existing file. Select New if you are creating a new database or Open if you want to open an existing database. If you are not sure, select New. If no dialog appears, from the File menu select either New or Open, as appropriate.

3. From the File menu, select Get external data, then Import.

4. In the first screen, select the proper directory, then type in the name of your file, for example, MAR99.TXT.
5. In the "Files of type" box, select Text files and click Import.

6. The next screen (Figure 8.6) prompts for type of file. Select Delimited and click Next.

7. The next screen (Figure 8.7) prompts for a delimiter type. Select
Tab, place a check in the check box that says First row contains field names, then click Next.

![Import Text Wizard](image)

**Figure 8.7. Delimiter selection.**

8. Next, specify whether the data should be placed in an existing table or in a new table (Figure 8.8). Typically you would put it into a new table, unless you are adding onto a table you have imported previously. If you select In an existing table, make sure that the data structure is exactly the same as the one you are importing or the import will generate errors. Unless you know that you have special requirements, click Finish. If you click Finish, you will bypass the next few optional settings and let Access
set the defaults. Otherwise, by clicking Next you can describe your data in more detail as follows.

9. The next screen (Figure 8.9) lets you optionally exclude data from the import process by excluding columns. You can also set other options such as whether an index should be built for a column, and what specific data type the column is. Click Next or Finish.

Figure 8.8. Field options settings

Figure 8.9. Optional field settings
10. Finally, you can assign a primary key to the new data table, let Access assign the key, or skip it altogether (Figure 8.10). Click Finish.

![Figure 8.10. Optional primary key setting](image)

You are now prompted for the name of the table to which to save the data. Either choose the default (same as the name of the file) or enter another of your choosing. Click Finish. File import is now complete and your new table is ready to use.
User Profiles

Audience: All users

Throughout the previous chapters that describe the TEG® Analytical Software, mention is made of the User profile that contains your operational preferences. This chapter describes how the user profiles are customized.

Your site administrator is responsible for setting up new users and for initial setup of user preferences.

The TEG® software is highly configurable. As background information: when the software is installed, a master configuration called “System setup” is done. As part of that configuration, users are defined with security user login names and optional passwords, along with all sorts of user default settings. However, you can specify your own preferences, which are stored in your User profile.

For example, you can perform the following customizations:

- You can specify the default name of the database to open, so that you don’t need to enter it each time.
- You can select which tests appear and set the order in which they are displayed in the Main screen and other screens.
- If you have a related test for which you wish to enter data, but the system does not contain that test, you can add it to your database.
- You can change the color of tracings and related textual information.

Note that there are different “types” of users defined within the software setup, and depending on your user type, certain options described here may not be available to you.

Customizing and setting up options
To set user options, select Options from the Main menu, then User Profile Setup.

![User Profile Setup Option](image)

The form opens to the Login tab, which allows definition of the defaults for the user currently logged in.

You can also access the other tabs for customizing the program to your own preferences, including the ordering of tests, adding sample types, and setting software preferences such as units for tests.

Select the appropriate tab for the type of setup you wish to perform.

Click Done when you are finished defining all types of preferences.

This is the default screen presented when you click on User Profiles.

![Login Preferences](image)

Enter your preferences for login. To identify the database, the Locate button operates the same as when you are logging in.
Select Tests to customize the tests used in the TEG® software.

Setting up tests

![Figure 9.3. Tests screen](image)

If a test you wish to view does not appear in the list, you can add it according to your own preferences using the Add button. First, however, you should check to see whether it has been excluded from the listing. You can choose the tests to display in any data panels that display test results. Click on Include to call the test selection dialog box.

![Figure 9.4. Include screen](image)

Place or remove check marks to select or deselect tests. Click OK when you are finished.

When you have selected tests and are back in the Tests screen (Figure 9.3), you can change the order of the tests by selecting a test, then clicking on either Move up or Move down as many times as needed to position it where you like.
If the test you are interested in was not excluded, but instead has not been defined, you can define your own tests by clicking on Add in the tests screen (Figure 9.3) and completing the dialog box that is presented.

![Add test screen](image)

*Figure 9.5. Add test screen*

You can later rename tests you have defined (but not TEG® parameters/tests), and change descriptions and units. You can also position them in any order as described earlier. These become additional data fields for entering blood sample results.

### Setting up normal values

This screen allows you to set or change normal values for the defined sample types. If the sample type you want to enter data for does not appear in the
pull-down list, click on the Sample Type tab to define a new one first, then return to this screen to enter normal values.

![Figure 9.6. Normal values screen](image)

If the test name for which you want to enter normal values is not present in the current display, select the additional test from the “Select a test...” at the right side of the tab.

![Figure 9.7. Add test to normal values screen](image)

You can only enter normal values for tests that are already defined. If the test is not yet defined, first define it as described under “Setting up tests,” then return to this screen to set up normal values.
Setting up software options

You can set how the program handles some of the software options through the options set in this screen.

![Figure 9.8. Set software options screen](image)

- **Data panel** - sets options for the data panel
  - *Show numeric data* - If checked (default), numeric data is shown on the data panel. If unchecked, the numeric grid is suppressed.
  - *Show clot* - If checked (default), the clot graphic is shown automatically on the data panel the first time the data panel is shown in a session. If unchecked, the clot graphic is suppressed and must be manually invoked. The clot graphic checkbox may be disabled if this feature is not available at your site.

  If both the numeric data and clot boxes are unchecked, only the sample identifying information is displayed in the data panel.

- **Maximized view** - sets options for maximized view
  - *Show grid lines* - If checked (default), horizontal reference lines are shown every 20 mm around the baseline. If unchecked, the grid lines are suppressed. The grid line color is set under the Video tab.
  - *Flash warning ranges* - If checked (default), the numeric display for critical clotting and lysis tests are flashed when they are outside the “trigger values”

- **Miscellaneous** - determines defaults for various program settings.
  - *Enable touch screen* - sets the default whether Touch screen is automatically enabled to expand certain dialog boxes to a more comfortable “touching” size.
- **Transfer QC samples** - determines whether quality control samples (sample types L1 and L2) are moved to the QC database out of the patients database. During installation this option can be set to transfer at sample completion or at program termination.

- **Quick print in black and white** - determines how the printer driver is used to represent color on your printer.

  - **FLEV units** - By default, FLEV is displayed in mg/dl, but can be changed to g/l.

  - **SP, R, and K units** - By default, the units are given in minutes. You can change this to seconds or millimeters with this option.

  - **Time Display** - Sets whether the time for samples is displayed using a 12-hour clock with the AM/PM indicators (default) or using a 24-hour clock. You can change these settings at any time, since the data is stored in the database using an internal format.

  - **Sensitivity** - The filtering level for for VCurve. It must be a positive odd number. This may not be available, depending on the SA settings.

  - **G Calculations** - Whether VCurve is calculated from A or G.

  - **Zoom level** - The VCurve tracing can be magnified in the tracing by using this value.

If tracings or tracing identifying information such as tick marks and reference lines do not display clearly on your computer, you can change the video settings for them in the Video tab.

### Setting video options

![Video options screen](image)

**Figure 9.9. Video options screen**
To change any of the elements listed, click on the element you wish to change. The tracing numbers in the middle panel represent the tracing order when multiple tracings are viewed in Maximized view. When changing colors, a color palette is presented, and you can select whichever color you wish with one exception: the sample tracing and background cannot be the same color. The bottom panel lets you change line types.

To reset the video options back to the system defaults, click on Reset.
Users of the TEG-enabled version of the TEG® software should first read Chapters 3-9 before reading this section, since the Remote version is embedded in the TEG-enabled version.

We also encourage you to read Chapters 1 and 2 for the theory behind the TEG® analyzer and the results it produces.
Chapter 10
Daily Operation

Set Up for Daily Use

Audience: Clinicians, TEG® operators, QA personnel

This chapter describes the daily operation of the TEG® analyzer. The procedures described here should be used in conjunction with the next chapter, “Sample Preparation” to effectively analyze patient samples. You should also observe good laboratory practices and all the guidelines spelled out in Chapter 13, “Quality Assurance.”

1. Turn on the TEG® analyzer by pressing the green power switch (See figure 10.1.)

Figure 10.1. Front of analyzer for daily setup
Allow the temperature for both columns to reach 37°C.
2. Check that the yellow motor switch is lit.
3. Make sure the cupwells are clean and dry. Clean with a cotton swab if needed.
4. Check the instrument leveling bubble. Adjust if not level by turning the level adjustment legs in the front (bottom left and bottom right) and back (bottom center) of the TEG® analyzer.

Loading Cups and Pins

Cups and pins are shipped in a styrofoam carton with a slide cover. Special attention has been taken to avoid any contamination of the working surfaces of the cup and pin. Do not touch the outside of the pin or the inside of the cup. Keep them in the styrofoam tray and covered when not in use. Disposable cups and pins have crush lines built into them so that they fit snugly into the cupwells and onto the spindle tip. The disposables are for single use only because the crush lines are spent after the first use.

1. Slide the carrier down to the platform, with the lever in the load position.
2. Pick up a disposable cup and pin from the styrofoam tray.
3. Place the cup with the pin still inside it firmly into the cupwell.

4. Carefully slide the carrier all the way up, being sure that the disposable pin is standing straight up in the cup so that the spindle tip can enter
5. When the top of the carrier is flush with the bottom of the column, push the pin firmly into place using the plastic pusher located at the bottom of the carrier. Counterbalance the analyzer by holding your other hand on top while pushing the pin.
Make sure that the pin is correctly loaded by checking that the bottom tip of the spindle is touching the inside bottom of the disposable pin.

6. Slide the carrier back down to the platform and push the cup firmly into the cupwell. The cup should rest flush with the carrier and should not pop up.

7. Input the information into the sample screen of the program. (See the section named “Inputting Sample Identifying Information” on page 147.)

8. Pipette the native or modified blood sample into the cup. (See Chapter 11 for information about preparing blood samples for analysis.)

9. Lift the carrier carefully to the pin with the lever still in the load position.

10. Slide the carrier up against the column.

11. Move the lever into the test position, resting your hand on top of the analyzer to prevent tipping.

12. Press [F10] or click on the start button on the computer keyboard to begin the test.
13. Repeat steps from #1 for each additional column.

Always use the proper precautions (e.g., gloves) when handling blood.

**NOTE:** A sample will terminate automatically when end-of-run conditions specified for the program have been met (see the siter administrator guide for more information).

Do not remove the sample from the analyzer before the sample is terminated on the computer, either manually or according to the options settings. Since the software is still calculating values, removal of the sample may cause spurious values to be written to the database.

1. If the test has not already been terminated by the software (according to the Options settings described in Chapter 14), end the test on the computer. (See the section named “Ending a sample run” on page 150.)

2. Return the lever to the load position and then press down to the eject position.

3. Slide the carrier down to the platform. Be sure the pin has dropped into the cup.

4. Press the carrier down firmly against the platform so that the plastic pusher located at the bottom of the carrier pushes the disposable cup out of the cupwell.

5. When the disposable cup pops up, lift it out of the cupwell and dispose of it properly.

To set the temperature on the TEG® analyzer, use the control buttons on the temperature controller, as described in the sections below.
As you set the temperature, observe the top reading which represents the temperature, and the columns are indicated as SP1 for column 1 (left) and SP2 for column 2 (right) below the temperature reading. Remember to wait for the analyzer to adjust to your new temperature before using the column you have set. You can change either column or both.

**To set column 1 temperature only:**
1. Press the index key (A in Figure 10.7) once. The column display changes to SP1. Using the up and down arrows (B), set to the desired temperature.

2. Press the enter key ©). The display flashes once.
3. Press the index key (A). The column display changes to SP2. Press the index key (A) again to exit. The actual temperature is displayed for both columns. Wait until the display readout matches the temperature you set within one half degree before using column 1.

**To set column 2 temperature only:**
1. Press the index key (A in Figure 10.7) once. The column display changes to SP1. Press the index key (A) again. The column display changes to
SP2. Using the up and down arrows (B), set to the desired temperature.

Figure 10.9. Setting column 2 temperature

2. Press the enter key ©. The display flashes once.
3. Press the index key (A) again to exit. The actual temperature is displayed for both columns. Wait until the display readout matches the temperature you set within one half degree before using column 2.

To set temperature for both columns:
1. Press the index key (A in Figure 10.7) once. The column display changes to SP1. Using the up and down arrows (B), set to the desired temperature.
2. Press the enter key ©. The display flashes once.
3. Press the index key (A). The column display changes to SP2.
4. Using the up and down arrows (B), set to the desired temperature. Press the enter key ©. The display flashes once.
5. Press the index key (A) to exit. The actual temperatures are displayed for both columns. Wait until the display readout matches the temperature you set within one half degree before using either column.

Hazard

Biohazards

Personnel using the TEG® analyzer should use powder-free examining gloves and should wash their hands immediately after removal of the gloves.
Fluid-resistant clothing should be worn while using the analyzer. The CDC has issued blood-borne infection control strategies, as have other health care agencies, and your institution has likely established a written infection control plan designed to minimize/eliminate employee exposure.

Even though the only working surfaces that routinely come into contact with blood are the plastic disposable cups and pins, any nearby TEG® surface that could be contaminated by a blood spill should be properly cleaned and disin-
fected with an appropriate disinfectant after completion of procedures, at the end of the work shift, and immediately after any blood spill.

Physical hazards

The moving part of the TEG® analyzer is a cylindrical cup, which oscillates very slowly through an angle of approximately 5º. Each rotation lasts 10 seconds. The analyzer operates at the low rated current of 0.42A, with a maximum power uptake of 50W. Therefore, there is essentially no physical hazard to the TEG® operator.
Sample Preparation

Audience: Clinicians, TEG® operators, QA personnel

The following sections describe the materials and procedures for operating the TEG® analyzer using different sample types. The use of a standardized method for the collection and handling of specimens is of utmost importance to ensure that TEG® results are reproducible and reliable. Haemoscope Corporation recommends that the user follow locally established procedures for the collection and handling of specimens.

Final blood volume in the disposable sample cup is 360µl unless specified otherwise in the product insert or other procedure. Notice that, depending on the sample type, you pipette between 330µl and 360µl into the cup, depending on whether you are running whole blood or modified samples, plus a fixed amount of an activator or modifier to bring the final volume to 360µl. These proportions are described below for modified blood samples and citrated samples.

Disposable cups and pins, as well as other analysis supplies are available directly from Haemoscope Corporation. For reliability and ease of use, activators/modifiers are available either in pre-treated disposable cup format or in pre-measured vials, depending on the reagent.

Native TEG® Samples

Materials

- Patient’s whole blood, no anticoagulant, assayed at four minutes after drawing sample, unless the sample is heparinized or sodium citrated. (Although the sample can be assayed between 4 and 6 minutes, normal values in the TEG® Analytical Software are based upon assay at 4 minutes.)
- Disposable cups and pins
- Pipetter(s) and tips
- Polypropylene test tube
Procedure

1. Make sure the TEG® analyzer is turned on and level, and the computer software is ready as described in Chapter 12.
2. Move through the initial screens of the program until you reach the Main Menu.
3. Click on the TEG icon in the local toolbar to bring up the TEG® Screen. We recommend that you input sample identification information at this point as pictured in the TEG screen and described in Chapter 12.
4. Observing proper precautions (e.g., gloves), prepare the patient’s arm for normal phlebotomy using alcohol sponge and sterile gauze. Apply tourniquet and make a clean venipuncture using a 19G butterfly needle. Discard the first 2-3ml, which contains tissue contaminants (but can be used for other, non-coagulation, testing). Attach a clean plastic syringe and gently draw 1-3 ml of blood. Start a stopwatch when blood first enters syringe. **Note:** For patients studied during surgery: To approximate results that would be obtained from peripheral blood, samples should be taken from the side port of the central venous catheter and not from the arterial catheter\(^{1,2}\).
5. Transfer the blood gently from the syringe to a small non-wettable surface, e.g., polypropylene tube. Avoid air bubbles and frothing. Do not shake.
6. At four minutes (on stopwatch) after drawing the blood sample, pipette 360µl of blood into the bottom of the cup.

Proceed with starting the sample analysis according to the instructions in Chapter 12, “Starting the Sample Run” on page 149.

**Modified Native TEG® Samples**

**Materials**

- Patient’s whole blood (assayed immediately and not later than four minutes after drawing sample, unless the sample is heparinized or sodium citrated.)
- Disposable cups and pins
- Pipetter(s) and tips
- Gloves
- Reagents (e.g., 1% celite, kaolin, ReoPro, heparinase, etc.).
Reagents, including heparin neutralizers, activators, platelet blockers, and antifibrinolytic agents, if available in treated cup format, are all processed the same way, by adding the blood sample to the appropriate treated cup:

Pipette 360 µl of native whole blood into the cup. Proceed with starting the sample analysis according to the instructions in Chapter 12, “Starting the Sample Run” on page 149.

When using reagents in vial format, add 1 ml of native whole blood to the vial containing the reagent (unless specified otherwise in a product insert or other procedure), cap and mix by inversion five times, and then pipette 360µl of the mixture into the TEG® cup. Proceed with starting the sample analysis according to the instructions in Chapter 12, “Starting the Sample Run” on page 149.

### Summary

<table>
<thead>
<tr>
<th>Reagent in cup</th>
<th>Reagent in pre-measured vial</th>
<th>Native</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-wettable surface, e.g., polypropylene test tube type</td>
<td>empty</td>
<td>empty</td>
</tr>
<tr>
<td>With reagent (invert 5 times)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Citrated Whole Blood TEG® samples

**Materials**

- Patient’s citrated whole blood (CWB)
- Disposable cups and pins
- Pipetter(s) and tips
- 0.2M CaCl₂
- Gloves

1. Using the two-syringe method and observing proper technique (e.g., gloves), with a 19G butterfly needle, draw and discard the first 3 ml of blood, then draw another 4.5ml of blood and transfer it to a blue-capped non-wettable surface tube containing 0.5ml of 3.2% (0.105 M) sodium citrate (pH7.4). Cap and mix blood with the citrate by gentle inversion three times. Note: Do not mix again until ready to assay. This is citrated whole blood (CWB).

   *Note: Use only non-wettable surface tubes. Polycarbonate tubes have a*
“wettable” surface that is highly polar and negatively charged, which can lead to sample platelet activation.

2. TEG® analysis should be done on the CWB within two hours of blood drawing. However, you should standardize on a fixed time (e.g., 15 min) to ensure reproducible results. (Note: if multiple testing is to be done on the same sample, add 750µl aliquots [per analyzer] of CWB into plastic microcentrifuge tubes. Cap and store at room temperature, without mixing until ready to assay.) You can also centrifuge the CWB before analyzing to obtain platelet rich plasma (PRP) or platelet poor plasma (PPP).

3. Pipette the following volumes of CaCl₂, depending on blood sample, in the cup:

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Volume of 0.2M CaCl₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>CWB</td>
<td>20µl</td>
</tr>
<tr>
<td>PRP or PPP</td>
<td>30µl</td>
</tr>
</tbody>
</table>

4. Mix blood by gentle inversion immediately before placing in the cup. Pipette the following amounts of blood to the cup.

<table>
<thead>
<tr>
<th>Sample type</th>
<th>Volume of blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>CWB</td>
<td>340µl</td>
</tr>
<tr>
<td>PRP or PPP</td>
<td>330µl</td>
</tr>
<tr>
<td>Modified (previously mixed with either heparinase, activator, Amicar, etc.)</td>
<td>360µl*</td>
</tr>
</tbody>
</table>

* unless specified otherwise in the package insert or other procedure. May require CaCl₂ or other additional modifier.

Proceed with starting the sample analysis according to the instructions in Chapter 12, “Starting the Sample Run” on page 149.

If multiple analyzers are being run simultaneously, this step is done on both channels of one analyzer before proceeding to the next. For example, mix the blood and add it to channels 1 and 2, and start the samples on the computer, then repeat for each additional pair of channels.

**Quality Control**

The TEG® analyzer has been shown to be a reproducible and reliable clinical tool when a good quality assurance program that includes proper phlebotomy techniques, careful sample preparation, and rigorous use of biological controls is followed.
For more details on Quality Control please refer to Chapter 13, “Quality Assurance.”


Audience: TEG® operators, QA personnel

This chapter is directed to TEG® operators who have a TEG® analyzer attached to their computer and will be running samples. The login procedure was documented in Chapter 4, but is slightly different for users who are logging in to run samples. The login procedure is described again, in full, in this chapter, with the additional requirements explained.

This chapter assumes that the software is installed and operational, and, if you are running on a network and must access a network database, that all the required network connections and drive mappings are in place.

This chapter also assumes that the channels connected to this computer have been activated through the Maintenance screen’s Setup tab. (See the Site Administrator’s Guide for more information.)

This chapter has some additional notations not used in the rest of the manual. In the outer margins, sharing space with the topic headers, you will notice additional text with icons. This text contains an icon with an instruction. You can scan these outer notations to complete the steps needed to run samples. The accompanying explanations contain more detail about each of those steps, along with illustrations of program screens you will see as you follow the procedure outlined.

These notations should be viewed as a summary, and you should be familiar with all the material in this chapter, as well as Chapters 10 and 11 that describe blood sample preparation and daily TEG operation, before running samples.

The notations used are:

<table>
<thead>
<tr>
<th>Icon</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>🔄</td>
<td>Perform blood sample operation</td>
</tr>
<tr>
<td>🔧</td>
<td>Perform TEG® analyzer operation</td>
</tr>
<tr>
<td>🔧</td>
<td>Perform software operation</td>
</tr>
</tbody>
</table>
**TEG Control or Not?**

The TEG-enabled version of the software can be used whether a TEG® analyzer is connected to your computer or not. For example, you might be running the software either in the lab or at a patient’s bedside, with an analyzer attached to run blood samples. The difference is that one user needs to control the TEG® analyzer (start samples, enter identifying information, end samples, etc.), while the other users wish to only view the data and have no analyzer attached to the computer running the software.

The difference operationally means that anyone needing to run TEG® samples must run the TEG®-enabled version of the software. This version contains the icons needed to access the TEG® screen, which is the analysis control point for the program. The remote version of the software does not have the needed icons.

Starting the program is the same in the TEG®-enabled version as in the Remote version.

**QC Databases**

When you log in with the TEG®-enabled version, you must specify a QC database in the login screen. This is because the software automatically maintains the biological control data separately from patient data. It does this by looking for samples that are identified as sample type L1 (Level I) and L2 (Level II), and moving them into the QC database when the sample terminates or when exiting the software program, depending on the user settings. See additional information about QC databases on page 149 and later in this chapter.

The QC database you use can be set in the User Profile so that it is automatically filled in at the login screen when your user name is entered.

**Quick Summary for Running Samples**

If the program is already running, proceed to the "Operator Login" section. Otherwise, this section summarizes the steps to run samples, the remainder of the chapter presents the details.

1. Start the program and log in, entering the QC database, if needed.
2. Click "Log In" on the Main toolbar for operator login.
3. Go to the TEG screen, enter sample info and start sample(s).
4. Exit TEG screen by clicking Done to view progress and results (also see Chapters 4 and 5 about viewing samples).
5. Terminate sample manually if needed.
6. Print reports.
Double-click on the TEG® software icon to start the program.

This is accessible either from the Windows Desktop or from the Start Button. First displayed is the splash screen showing the program title and copyright information.

It disappears in a second or two, or you can click on it or press any key to clear it. Next, you must log in to gain access to the system.

The login screen collects information about the user logging in. You identify yourself with your user name and password, and select the database you will be using, and check the TEG mode box.

The login screen is shown here:
These steps are described in more detail in the sections that follow.

Enter the user name and password you were assigned. Your user name can be entered in either upper or lower case, but the password, if used, is case sensitive. For example, if your password is Lola, you must enter it with the upper case L. When you type the password, it is echoed to the screen as asterisks and is never displayed.

*Shortcut tip: In many cases, such as when you are not using a password, just typing the first character of your user name, followed by clicking OK or pressing the Enter key will log you in, set your database, and take you to the Main screen.*

Database selection

The login process requires that you identify which database you want to access to view, store, or otherwise access patient sample data. TEG-enabled users are also required to specify a QC database name.

Usually, the default database names are correct, but if you wish to use a different database, you can either create a new one or use one that already exists. Click on OK to complete the login process.

To create a new database, click on the New button, and the system prompts whether you want a patient database or a QC database. If you are creating a new database because you wish to run samples, create a patient database.

![Database type selection](image)

*Figure 12.4. Database type selection*

If you are setting up both a patient and a QC database, you will go through this process once for each database.
Choose a directory name (usually c:\teg) and type in the name of the new database in the File name field (for example, surg120600):

The program will automatically append the extension TEG to the filename to identify it as a patient database.

If you are creating a QC database, the system will automatically append QC to the filename to identify it as a QC sample database.

To access an existing database, type its name, including the path (e.g., C:\MYDB\SURG.TEG) into the “Patients database” field, or click the Locate button to search for the database you want.

Clicking on Locate brings up location options including Find, Browse, and Cancel.
- **Find.** Search an entire hard drive for any TEG® databases. To Find databases, select a drive letter and then click on Find to begin the search. If your hard drive is C:, you can click Find without selecting a drive letter first.

![Figure 12.8. Search a drive for a database](image)

Click on the desired database name when it is displayed, then on Done. If your hard drive has many folders and/or files, it may take a few minutes to locate all the databases.

- **Browse.** Browse lets you traverse the directory tree to locate your database.

![Figure 12.9. Browse for a database](image)

Use the Windows’ standard browse method to find the path and database, first navigating to the drive and folder, then selecting a database name by clicking on it. Then click on Open.

- **Cancel.** Return to the login screen without making a selection.

### Login Preferences

As part of your user preferences (based on your user name and password; described earlier in this chapter), you can define the default name and location of both databases. Setting these preferences automatically fills in these fields for you as you log in. You can override the preferences for any of these items...
as you log in by entering different information or checking/unchecking the box. User preferences are described in Chapters 9 and 14.

Before you can enter any information into the system, you must log on with your operator ID. The TEG® software maintains an audit trail of all database operations and requires an operator ID to track this information. To enter your ID, click on the Logon icon in the Main toolbar.

Figure 12.10. Logon icon

This displays the Operator login screen.

![Operator ID login screen](image)

Select your Operator ID, enter the password, if any, and click on Logon to continue. The logon icon is then disabled in the Main toolbar. Note that if you use a bar code scanner, you can scan your Operator ID from a badge, etc., providing it is the same as is defined in the software.

Note that depending on the configuration, more than one operator can be logged in at a time. This allows different people to run samples without having to exit and restart the program. If multiple logons are allowed, the logon icon remains enabled to let other operators log on.

When you are finished running samples, use the Logout icon to log out of the program. If multiple operators are logged on, select the operator to log out when the logout screen is presented.

You must be in the TEG screen to start samples.

To access the TEG screen, click on the TEG icon in the local toolbar:

Figure 12.12. Click the TEG icon to enter the TEG screen
The TEG screen shows the sample id information for all available TEG® channels (as set up through the Maintenance tab under the Options menu), in ascending order. In addition, it lists a summary of how to run a sample on the 5000 series TEG® analyzer.

Available channels have a bright yellow background, active channels (running samples) have a green background. The channel currently selected has a cyan (blue) background. If the selected channel is active, it still has a cyan background, but the “Active” indicator at the bottom of the screen flashes slowly.

When a sample ends (either manually or by program settings), it is removed from the TEG screen.

If no keyboard or mouse activity occurs for the time period set by your Site Administrator, the screen blacks out and displays the Operator Login screen. This is to prevent unauthorized access to patient information. During this time, any samples that are running will continue to run without interruption, but any other activity will require logging back in as described earlier under "Operator Login."

Running a Sample

Patient and sample information should be entered before a sample is run. If this information is not available until later, you can enter the information either before or after you start the sample.

Running a sample consists of:
☐ drawing and preparing the blood sample

☐ performing software operations (see the following sections for details):
  ■ Selecting a channel in the TEG screen
  ■ Inputting sample identifying information

☐ placing the blood sample on the analyzer

☐ starting the data collection

Alternatively, in an emergency situation, you can start the sample and input the sample identification data later. If you do not enter sample ID data before the sample ends, you are prompted to do so when the sample run completes.

Note that you can input sample identifying information without running the sample at this time. When you have entered the data but have not started the sample, this is referred to as a pending sample.

Channels are listed in numerical order by default. Select a channel by clicking in the sample identification area for that channel, then enter the identifying information for that sample. Note that you cannot change the channel number. To change the default sort order, click on one of the headings (e.g., Patient name) to re-order the display. To sort in descending order, click on the heading again. To return to the default order, click on Channel number.

If you are using a touch screen, select a channel by touching the sample ID area, then on the Touch icon in the Main toolbar, which magnifies the sample id area so that it is more easily “touchable.”

You can move between channels without the mouse or touch screen by using the Tab key to move forward, and Shift+Tab to move backward. Each press of the Tab key moves to the field for a given channel, then proceeds to the next channel.
Input patient name, sample type and description in any order:

You can input this data in any order.

Sample type

The sample types listed here are controlled by your user profile. You can define additional sample types or exclude sample types as described in Chapter 14. You can also set the order in which they are listed in the pulldown menus.

Select a sample type

Select a sample type from the pulldown menu.

Patient name

Select a patient from the pulldown menu.

Select or input a patient name.

If the patient’s name is not in the list, you can type it in, last name and then first name, separated by a comma. When you leave the name box, if it is a new patient name, a message prompts whether you want to create the new patient in the database.

If you respond with yes, another screen is presented for entering patient ID (required). You can enter other optional information (see the section named “Creating a case” in Chapter 6 on page 87). Click on Done to close the Patient window. If you do not select a Procedure at this time, then it will be left blank.

If you respond with no, the program returns to the main screen, and you can select a patient from the list.

If you are using a touch screen, you will need to use the keyboard to type in the patient name if it does not exist in the pulldown list. (If you are using Windows XP, you can use an onscreen keyboard to do the typing.)

If you have a sample that is bar coded, and you have a barcode scanner attached to your computer, you can scan the patient id instead of selecting or typing a patient name.

First click, as usual, on the channel for which you are entering data. Then click on the Scan icon in the Main menu and scan the sample barcode.

Figure 12.15. Click the Scan icon to scan patient ID

If the patient already exists in the database, the patient name is displayed in the data panel. If the patient does not exist, a dialog box is presented that asks you to input the first and last name. Click on Done when you are finished entering the name.
Select a sample description from the pulldown menu or type an optional short description of the sample.

This sample description is displayed with the tracing in the tracing panel and is printed with the tracing on reports. You can enter lengthier descriptions with the notes feature described in Chapter 4.

We recommend you use the pulldown list for the description. Otherwise, over time, the list may be filled with undesirable entries. To remove these entries, you will need to access individual samples that have the description, highlight the description, and delete the description. Deleting all samples using that sample description will also remove it from the dropdown menu.

For QC samples (sample type L1 or L2 for Level I control and Level II control, respectively) use the “Name” field for the lot number of the control. Although you can enter this information in any order, you can save a step or two by entering the QC sample type (L1 or L2) first. Then, the pulldown menu for the name displays lot numbers instead of patient names. Just like entering a new patient, entering a new lot number brings up a dialog box to enter all the needed information about the lot number.

See the section named “Exiting the program” at the end of this chapter and Chapter 13, “Quality Assurance” for more information about QC procedures and how the TEG® software handles QC samples.

Draw and process the blood sample according to the instructions given in Chapter 11, Sample Preparation.

Place sample on analyzer, raise the carrier, and put the lever in Test position as documented in Chapter 10, Daily Operation.

To start the data collection for a sample, make sure the correct channel is selected, then either press F10 or use the toolbar Start icon:

You can only do this from the TEG screen.

You will know that the sample has started when the background for Channel number changes to green, and the cursor moves to the next channel.

In some instances, when you start a sample, a message about “eTest out of range/Disposable misload” may be displayed. See the Troubleshooting Guide in Appendix D.
Ending a Sample Run

Samples are automatically ended when the end-of-run setting specified in your user profile has been satisfied; for example, when A60 is finalized (default), when MA is achieved, or after a fixed time has elapsed (such as 20 minutes), or when some other test has been calculated. See the section named “Setting software options” in Chapter 14 for more information.

When a sample ends normally or is stopped manually, it is removed from the TEG screen display. DO NOT remove a sample(s) from the analyzer before the sample is terminated on the computer, either manually or according to the option settings. Since the software is still calculating values, removal of the blood sample may cause spurious values to be written to the database.

To stop a sample before its programmed end, select the sample and then click on the Stop icon in the main toolbar or press F11.

You will be prompted to end the sample or continue running it. If you have not entered patient and sample information, you are prompted to do so now. You will be asked to confirm the end the sample.

All samples are automatically saved to the database whether they end automatically or are stopped manually. If you do not want to keep the sample, delete it by following the instructions in the section named “Deleting records” in Chapter 6.

Accession number

Page 67 in Chapter 5 describes the Sample detail tab because it contains additional information about the sample, including interpretation. One item of special interest to laboratories is the Accession number for a sample. This in-
formation can be entered in the Sample detail tab. A shortcut method to access this tab is to click on the Status bar.

![Sample detail tab]

**Figure 12.17. Accession number in Sample detail tab.**

To exit the program, select File in the Main menu, then Exit.

When you are running the TEG®-enabled version of the program, the system checks for several conditions to avoid loss of data, and issues prompts, if needed, before it exits:

1. First, it checks to see whether you have any active samples. If yes, you are prompted to end the runs.

![Exit program]

**Figure 12.17. Confirm sample end**
If any samples have not been identified, you are prompted to enter that information.

This screen identifies which channel is missing identifying information. You can select an existing patient, then click Done. Additional choices are:

- **Create** to create a new patient
- **Ignore** to skip patient identification. This inserts the current date and time into the patient name area, and will typically not be meaningful and should only be used in emergency situations. You should go back at a later time and either delete these samples or enter identifying information for them. This option is site-configurable, and may be set to require selection of a patient.
- **Cancel** to stop the termination process and continue running the samples.

This sequence is repeated for each channel that is terminating without ID information.

Last, it checks to see if you have any quality control samples (sample types L1 or L2) in this database. If yes, it moves those samples to the QC database, if the option for transfer is set in the User profile, which it is by default. Normally QC samples are transferred as the sample ends, but the program can be configured to transfer samples at program termination instead, and are transferred when the program ends. In the event that the lot numbers do not exist in the target QC database, you are prompted whether you want to automatically create those lot numbers from ones in the patient database or whether you want to add new lot numbers and review your data.
The TEG® analyzer has been shown to be a reproducible and reliable clinical tool when a good quality assurance program that includes proper phlebotomy techniques and sample handling is followed.

The TEG® analyzer is classified by the FDA as Moderate complexity.

This section describes methods that provide comprehensive quality assurance for the TEG® analyzer based on the recommendation of the US Clinical Laboratory Improvement Amendments (CLIA), CLSI, and the excellent performance standards of the TEG® analyzer. Following these methods assures users, clinicians, and their patients of reliable performance of their instruments.

The use of a standardized method for the collection and handling of specimens is of utmost importance to ensure that TEG® results are reproducible and reliable. Haemoscope Corporation recommends that the user follow locally established procedures for the collection and handling of specimens. Everyone using the TEG® analyzer should be familiar with standard laboratory procedures, techniques, and precautions, particularly those that affect hematological testing, as well as with the operation and precautions for the TEG® analyzer, and how samples are applied and removed (as shown earlier in this manual). Users should also abide by Federal, State, and local guidelines for assuring quality control in clinical laboratories.

These laboratory techniques and precautions include:

- Maintaining training and proficiency testing schedules, and recording results in personnel files.
- Observing safety requirements for handling blood.
- Using the two-syringe technique by the phlebotomists (described in Chapter 11) to eliminate tissue fluids or contamination of catheter lines.
- Avoiding heparin contamination. If the catheter line is loaded with heparin or coated with heparin, a heparin-like TEG® tracing will result unless...
precautions are taken to eliminate the heparin either before or after the phlebotomy. We strongly recommend the use of heparinase to eliminate heparin contamination.

- Avoiding clot activation in the drawn sample by exposure to non-wettable surfaces. The blood from the plastic syringe must be transferred to a non-wettable surface (e.g., polypropylene) test tube only, unless the glass vial has been siliconized to prevent activation.

- Adhering to the time intervals established for native whole blood analysis. Blood samples should be placed on the TEG® analyzer at 4 minutes after withdrawal if they have not been sodium citrated or heparinized for longer storage.

- Avoiding touching of the working surfaces of the disposable cups and pins before sample applications.

Finally, an effective quality assurance program requires that you keep and regularly review records. The TEG® software is set up to maintain these records and even to transfer QC data to statistical computer packages for analysis.

### General Quality Control

Quality control for the TEG® analyzer consists of the following areas:

- Maintenance and function checks
- Calibration and calibration verification
- Control procedures

Each of these quality control areas is discussed in the following sections.

### Maintenance and function checks

Mechanical, electronic, and operational checks verify the proper test performance and test results reporting for the TEG® analyzer.

#### Mechanical

Alignment of the TEG® columns and calibration of the analyzer verify and/or maintain the mechanical functioning of the analyzer. These mechanical function tests and adjustments are performed at least semi-annually by trained TEG® users or Haemoscope technicians. See the TEG® Service Manual for details.

#### Electronic

The eTest determination/adjustment of the TEG® analyzer verifies and/or maintains the electronic functioning of the analyzer. The frequency, materials, and procedure for TEG® electronics testing are described in the next section.

Each of the maintenance functions are applied to individual channels on a TEG® analyzer. The type of analyzer is identified for each channel. If you at-
tempt to run a maintenance function before you select a machine type, you are prompted with the following screen to select your machine type:

![Machine type](image)

**Figure 13.1. Select TEG model**

Click on the image that belongs to your analyzer. A type only needs to be entered for one of the pair of channels belonging to a analyzer. It is automatically copied to the other channel.

**Electronics Testing (eTest)**

Frequency:

☐ Daily.

Whenever the biological controls do not produce results within the specified ranges, the first troubleshooting test is to run eTest.

**Materials needed:**

☐ trimmer adjustment tool (provided by Haemoscope Corp.)

**Procedure:**

Select Options, then Maintenance from the Main Menu.

![Options](image)

**Figure 13.2. Maintenance option**
1. Select the channel you wish to test and click on eTest.

2. Move the lever to the Test position.

3. Wait until the program issues the eTest status message.

<table>
<thead>
<tr>
<th>Message</th>
<th>Cause/Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at equilibrium</td>
<td>This might be due to environmental factors or too much vibration. Try turning off the motor.</td>
</tr>
<tr>
<td></td>
<td>If the message is repeated, the analyzer might be unsteady and should be stabilized.</td>
</tr>
<tr>
<td>eTest out of range</td>
<td>Adjust it with the trimmer adjustment tool using the adjusting screws on the back of the analyzer labeled BASE that correspond to the column you are working on. See figure 13.4. The analyzer is labeled with arrows indicating which way to turn the screw to increase the reading. Turn in the opposite direction to decrease it.</td>
</tr>
</tbody>
</table>

The acceptable range for the eTest value is between 1800-2300.

When the reading is within range, the computer issues the message:

**eTest is OK**

If the eTest is OK, check the next channel until all are tested before you begin running samples.

If the eTest value is out of range, adjust it with the trimmer adjustment tool.
tool using the adjusting screws on the back of the analyzer labeled BASE that correspond to the column you are working on. See figure 13.4.

![Figure 13.4. Back of the TEG analyzer with connector and adjusting screws](image)

To raise or lower the values, turn the screws in the direction indicated by the arrows above the screw.

If you have problems adjusting the baseline readings to within range, please contact your local service representative.

The second column in Setup tab in the Maintenance screen stores the serial number of the analyzer for that channel. Serial numbers are required. The serial numbers are stored in pairs, so that whatever you enter for one channel is automatically copied to the other channel for that analyzer. For example, if the serial number for channel 3 is entered as A123, then A123 is automatically copied to channel 4. The serial numbers allow full maintenance history reports to be generated for each analyzer.

Several types of reports on the maintenance for TEG instruments are available. See the section named Quality Assurance Reports on page 163.

The report is presented in print preview and can be printed by clicking on the printer icon at the upper left of the screen, as described beginning on page 58 for printing TEG® samples.

Use of biological controls serve as the operational check for the analyzer and are the basis for monitoring the quality control of the analyzer. See the section named Control Procedures below.

As part of the normal quality assurance protocol, these checks should be documented so they are readily available for review. You can print the Maintenance history report through the Maintenance screen, as described above.

As mentioned in the Maintenance and Function Checks section above, calibration testing and adjustments to the analyzer are performed at least semi-annually by trained users or Haemoscope technicians.
To verify calibration, calibration materials must be assayed in the same manner as patient samples. Use of biological controls serve as the calibration verification for the TEG® analyzer. See the section named Control Procedures below.

Control procedures

Use of biological controls, which serve as the operational check and calibration verification, is the basis for monitoring quality control of the analyzer and both levels should be run each shift (or as otherwise dictated by your institution’s policy) before running other samples to assure that all analyzer settings are within range. Such use of biological controls provides a standard of reference for normal and abnormal coagulation patterns. See the description of these controls in the next section named “Biological control output,” below.

The test results for the biological controls should be entered into a separate database for easy access. This control data can then be exported for analysis by a statistical software or spreadsheet package, as documented in Chapters 7 and 8.

Biological control output

Haemoscope makes available two biological controls named Level I and Level II to use in your quality control protocol. These controls contain animal citrated whole blood, including platelets and plasma, stabilizers, and buffer. They contain no human material. The controls are lyophilized, and you reconstitute them with distilled water before use. The package insert provides full details on their preparation, use, and expected results. With each new shipment of controls, check the insert for possible changes in the ranges.

Level I has been formulated to simulate a normal blood sample, while Level II simulates an abnormal sample of a bleeding patient. For example, running the Level II control produces the following tracing:

![Figure 13.5. Level II abnormal tracing](image)
Compare this to a normal tracing:

![Figure 13.6. Level I tracing example.]

Tracking the results of the Level I and Level II controls will help document the reliability of results obtained from patient samples. Patient results should be considered unreliable when the controls produce tracings that are out of their usual ranges, and should not be reported until this is corrected.

Failure to obtain the expected value may be an indication of biological control deterioration, TEG® analyzer, or procedural problems. Check the eTest, and if correct, re-run with a sample using a fresh vial of Level I and Level II controls and fresh calcium chloride. If the results are still abnormal, contact technical support.

Haemoscope Corporation provides all the needed accessories and consumables for use with the TEG® analyzer. These materials have all been produced under strict specifications and stringent quality control guidelines and are strongly recommended for use with the analyzer. Unless otherwise specifically stated, use of other sources for consumables may void your warranty.

This section discusses how the TEG® software handles the data for the biological controls.

The TEG® Analytical Software handles the tracking of biological control samples for L1 (for Level I) and L2 (for Level II) sample types in a special way. You run these samples in whatever patient database you wish, and when the sample ends, the data for the QC samples is automatically written to the QC database. (This action can be disabled through the configuration settings by...
the Site Administrator.) The results are placed in a database named QC.QC, unless otherwise specified in the configuration settings or during login. Unless there are special circumstances that require the QC samples to remain in the patient samples database, we recommend that you leave the defaults in place.

**You must run quality control samples from within a patient database.**

The software provides an option that is configured by the site administrator that defines the time interval between QC alerts. The alert is displayed when it is determined by the software that the interval has elapsed since the last QC sample has run.

**Only samples having sample type L1 or L2 are automatically moved to the QC database.**

When running QC samples, define the sample type to be L1 or L2 and select the lot number from the list for Name. If the lot number does not exist, you can type it into the Name field. Alternatively, to more fully describe the information for that lot number, click on QC > Lot number in the Main menu to bring up the lot number dialog:

![Lot number selection or addition](image)

*Figure 13.7. Lot number selection or addition*
Select Add lot number to bring up the lot number information dialog:

![Enter lot number information dialog](image)

*Figure 13.8. Lot number information*

To update lot number usage dates, you select “Manage” as shown in figure 13.7. The same screen as shown in figure 13.8 is displayed, with the lot number and sample type filled in, along with whatever dates may already have been entered.

Typically after entering a new lot number for a sample type (either L1 or L2), you should check the insert for the new lot number’s normal ranges to see if they differ from the old lot number’s. This is done through the Options menu, User profile setup.

![Options menu](image)

*Figure 13.9. User profile setup option*

Select the Normal values tab, and enter new normal ranges if needed.

The old values can be saved first into the QC database with the Archive button (as shown earlier in figure 13.7), so that a history of the normal ranges is maintained for the biological controls.

Several report types can be generated to track the performance and service history of the TEG system.
Lot number history

A log of the lot numbers and usage dates is available from the QC menu, Report option.

The report is presented in print preview mode, and can be printed as described on page 62 for TEG® samples.

Levey-Jennings report

The Levey-Jennings report is available from the QC menu, Levey Jennings option.

The Levey-Jennings report provides a graphic review of each of four main tests for the L1 and L2 biological controls by displaying for each test the daily test values in a ± 3SD scale that makes it easy to spot shifts and out-of-range results. A sample monthly graph for the MA test is shown below. The mean value is 52.0mm, and three standard deviations are shown above and below the mean. Note that on the 10th of the month, two values fell outside -3SD, and on the 13th and 14th, values fell outside +3SD.

The report also lists the numerical results, operator ID, and corrective actions entered at the time of out-of-range QC. When out-of-range QC results are detected by the software, a dialog box is presented to the operator to identify corrective actions. (Out-of-range is defined as more than one out of the four test values – R, K,
alpha, or MA – being outside the normal range.) A sample of this portion of the report (for different samples) is shown below.

### TEG® Analyzer QC Summary Report

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Y (mm)</th>
<th>X (mm)</th>
<th>Angle (deg)</th>
<th>Ha (mm)</th>
<th>Op</th>
<th>Action</th>
<th>Ch</th>
<th>SN</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/6/2004</td>
<td>10:36:57AM</td>
<td>3.25</td>
<td>1.26</td>
<td>76.32</td>
<td>34.19</td>
<td>Temp</td>
<td>Approve</td>
<td>1</td>
<td>5011-072-EB</td>
</tr>
<tr>
<td>5/6/2004</td>
<td>10:28:57AM</td>
<td>3.48</td>
<td>1.50</td>
<td>79.10</td>
<td>35.10</td>
<td>Temp</td>
<td>Approve</td>
<td>2</td>
<td>9911-072-EB</td>
</tr>
<tr>
<td>5/6/2004</td>
<td>10:37:22AM</td>
<td>3.40</td>
<td>1.67</td>
<td>80.10</td>
<td>35.10</td>
<td>Temp</td>
<td>Approve</td>
<td>3</td>
<td>9911-072-EB</td>
</tr>
<tr>
<td>5/6/2004</td>
<td>10:37:22AM</td>
<td>3.25</td>
<td>1.50</td>
<td>77.10</td>
<td>35.10</td>
<td>Temp</td>
<td>Approve</td>
<td>4</td>
<td>9911-072-EB</td>
</tr>
<tr>
<td>5/6/2004</td>
<td>10:37:22AM</td>
<td>3.25</td>
<td>1.50</td>
<td>77.10</td>
<td>35.10</td>
<td>Temp</td>
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</tr>
<tr>
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<td>10:37:22AM</td>
<td>3.25</td>
<td>1.50</td>
<td>77.10</td>
<td>35.10</td>
<td>Temp</td>
<td>Approve</td>
<td>6</td>
<td>9911-072-EB</td>
</tr>
<tr>
<td>5/6/2004</td>
<td>10:37:22AM</td>
<td>3.25</td>
<td>1.50</td>
<td>77.10</td>
<td>35.10</td>
<td>Temp</td>
<td>Approve</td>
<td>7</td>
<td>9911-072-EB</td>
</tr>
</tbody>
</table>

**Figure 13.13. Daily numerical results in Levey-Jennings report.**

You can view a log of daily maintenance runs (eTest and Calibration) through the Maintenance screen by clicking on the Report button, and then selecting Daily log in the report options screen displayed.

The daily results are listed, along with any service notes that fall within the date range selected.

Note that you can filter by date and/or instrument serial number.

A report on the service history can be printed by clicking on the Report button in the Maintenance screen, then selecting Service history. The service history is entered in the Maintenance screen when performing calibrations and alignments. You can also select to print any notes entered by technicians during the service call by clicking in the box to Display notes.

You can view the contents of the QC database, except when samples are running on that computer. When you are viewing the QC database, you can use the filters, export data, and print tracings using the steps outlined earlier in chapters 5 through 7.

To switch to the QC database, click on QC in the main menu, then select...
Go To. A check mark will appear in front of Go To and the database switch will occur.

![TEG® Analytical Software](image)

*Figure 13.14. Go to QC database option*

You cannot start or stop samples from within the QC database.

To return to the patient database, click on QC in the main menu, then unclick Go To. The samples from the patients database are restored to view.

You can tell whether you are in the QC database or the patient database because the database name is displayed in the program title bar at the top of the screen next to the program name. Patient database names end in TEG and QC database names end in QC.

**Local normal ranges**

The normal ranges provided by Haemoscope Corporation represent a heterogeneous population of normal control patients. It is possible that different population composition, for example, all females or smokers, may produce a different set of values for normal ranges. For this reason, we suggest that you initially run and analyze samples from a group of 10 to 20 “normal control individuals” to provide your own local normal reference ranges. These individuals should be healthy and not taking any medications such as aspirin, NSAIDs, or birth control pills, etc., which affect hemostasis.

If the statistical analysis results do not correspond to those released by Haemoscope Corporation, we would be happy to review your results and participate in further analysis.

**Quality assurance summary**

These testing and checking procedures combined with an effective training and proficiency testing program form a comprehensive program of quality assurance for the accuracy of the electrical and mechanical output of the TEG® analyzer and the reproducibility of the data, and assure compliance of the entire system.

**Operational checks & maintenance guidelines**

Haemoscope recommends adhering to the following operational checks and maintenance guidelines for the TEG® analyzer:
Daily:

- Biological controls (operational and calibration verification)
  Print tracings, sign, and file.

  - Level I (normal) control sample run
    - The sample run is considered satisfactory if three out of the four coagulation parameters $\beta$, $K$, $\alpha$, and $MA$) are within the ranges specified in the product insert.

  - Level II (abnormal) control sample run
    - The sample run is considered satisfactory if three out of the three coagulation parameters $\beta$, $\alpha$, and $MA$) are within the ranges specified in the product insert. Since Level II represents an abnormal (hypocoagulable) blood sample and produces low MAs, the $K$ parameter may not be determined.

- Electronics testing (eTest)

- Haemoscope recommends that two levels of controls be run at least daily. Your institution or other guidelines may recommend more or less frequent testing.

Every six months:

- Maintenance and function checks
  - Routine maintenance consisting of mechanical and electronic validation/adjustment and calibration by trained users or Haemoscope Corporation technicians
  - Maintenance history report (described on page 159) to document maintenance procedures should be reviewed and filed for reference.
Chapter 9 in the Remote software section of this manual described user profile configuration. Since the TEG-enabled version of the software includes the Remote version, all the configuration options described there apply to users of the TEG-enabled version. Additional options are available to TEG® operators, including setting up new sample types, setting sample run and termination options, etc. These additional options are presented in this chapter.

If the sample type you wish to use for assigning normal values or for use in the pulldown menu in TEG mode does not appear in the sample type list, you can enter a new one here. (See also the Include option, described next, to make sure the sample type has not been excluded from display.) Click on the Add command button.

![Sample type setup screen](Figure 14.1. Sample type setup screen)

Enter a short name in the “Define new sample type” text box, since only the first two or three characters appear in the Main screen. In pull-down lists that show sample type, the short name appears with the longer description you de-
You can enter more extensive comments in the other field for documentation purposes. Click OK when you have completed the definition.

![Add sample type](image)

*Figure 14.2. Add sample type*

**Include**

You can include and exclude sample types, just as was described in Chapter 9 for tests, by checking and unchecking them in the Include screen.

**Sample type order**

You can set the order that sample types are displayed in various pulldowns by using the Move up and Move down buttons after selecting a sample type.

**Setting software options**

A set of software options were described in Chapter 9 for remote users. Operators running the TEG-enabled version of the software have additional software options that can be configured, as presented at the bottom of the Software options tab.

Note that if you change these settings while a sample is running, the setting may not take effect until the next sample is started. For example, if you change the angle calculation method and the angle has already been calculated, it is not recalculated for running samples; or if you change the run ter-
mination criteria and the criteria you specify has already been met, the run may not terminate according to the new criteria.

These additional options are:

- **Angle Calculation** - The angle can be calculated either using SP or R:
  - Angle measured from SP to curve (default)
  - Angle measured from R to the curve

- **MA Calculation**. MA can be calculated in two different ways.
  - **Absolute MA** - calculates the actual MA, determined by one of the following, as soon as any one of them is true:
    - No change in measurement 60 times in a row at a rate of every 5 seconds or
    - The last 20 measurements fall below the maximum 10 times and never rise above it or
    - The value falls below the maximum 5 times and the last reading is at least 2 mm than the maximum
  - **Small deviation MA** - calculates MA when the readings of the amplitude (after $\alpha$ has been established) stay within 1 mm for at least X minutes. When you select this method for MA calculation, a text box asks you to select the value of X. The default (in minutes) is 3.

The preferred setting is Small Deviation MA because this allows you to obtain the MA value early without clinically affecting the result, calculate the LY30, LY60, and CI faster, and get an accurate time to MA. Insignificant change in MA (such as .5 or 1 mm) as the tracing proceeds...
(over X minutes) is not clinically significant. These changes can be caused by any number of factors, including vibration of the analyzer or electrical interference.

☐ **Com port** - selects the RS232 serial port that the TEG® analyzer is connected to.

☐ **Run Termination** - By default, a TEG® run is automatically terminated (and the data is written to the database) after A60 and LY60 have been computed, one hour after the value of MA is established. This option lets you change the termination criterion either to a fixed time value or to the calculation of a different parameter.
Specifications and Performance Characteristics

- Minimum computer configuration: Pentium III PC with 1G MHz or higher processor; 256 MB RAM; 9-pin COM port available for A/D connection; running Microsoft Windows 98 or higher, including Windows 98, NT 4.0, 2000, XP, plus Windows Internet Explorer 4.02 SP2 or higher. Additional COM ports may be needed for touch screen, bar code scanner, and/or LIS interface (if any of these are anticipated).

- Color monitor and SVGA (or higher) video board running at 16-bit depth or higher

- Any Windows supported printer for color or black and white output

- CD-ROM for installation of software (CD-RW recommended for backups or data transfer)

- Operating network connection using any Windows-compatible network, if using network-accessible database (e.g., Remote version of software)

- A/D box, cables, and software

- Uninterruptable Power Supply (UPS) recommended.

2 independent measuring channels.

Cup drive - line-synchronized, with synchronous motor

Temperature control - Individual temperature control for each column

Measuring technique - Shear elasticity of a coagulating sample, determined by motion of cup.

Transducer - Electrical-mechanical transducer of movement of torsion wire connected to the suspended pin.

Sample Volume - 0.36ml to 0.38ml

Power - power supply in protection class I, transformer with thermal cutoff and monitored safety insulation resistant to tropical conditions. Power supply must be plugged into a properly grounded outlet.
220V model- operating voltage 230V, 50 Hz, rated current 0.20 A, max input power 46W. Thermal cutout and 1 A Slow Blow IEC fuse provided.

120V model- operating voltage 120V, 60 Hz, rated current 0.38 A, max input power 46W. Thermal cutout provided.

TEG 5000 input power rating (from power supply) 24 VAC 30 W.

A label on the back of the TEG® analyzer, as part of its identifying information, contains the following warning symbol and instructions to use the analyzer with the power adapter provided by Haemoscope Corporation:

⚠️ Use only Haemoscope power adapter

Initial Warm up time - 5 minutes to warm sample cups/pins

Operating position - level adjusted by leveling feet and level

Environment - vibration free position, no solar radiation, operating temperature +10 to +35°C, storage temperature -30 to 50°C, relative humidity 20-80% (non-condensing).

Dimensions - 29cm (11.4 in) x 22cm (8.6 in) x 18cm (7.0 in).

Weight - 5.4kg (12 lb)

Environmental

Indoor use

Mains supply fluctuations not to exceed ±10% of the nominal voltage

Permissible environmental conditions for transport and storage are: -30°C to +50°C

Maximum relative humidity 5-95% (non-condensing)

Overvoltage Category II

Pollution Degree 2

Performance Characteristics

Through performance testing, the accuracy and precision of the TEG® 5000 Series analyzer is supported. In addition, Haemoscope has identified reference normal ranges as well as factors that may affect the measurement capability, performance, and sensitivity of the analyzer. A summary of the accuracy, precision, sensitivity, and normal range characteristics for the TEG® 5000 Series analyzer are discussed below. Following this discussion, performance information regarding the Functional Fibrinogen Level Test is presented.
outlined in the User’s Manual and using the same TEG® software. The following four parameters, which are collected during routine TEG® use, were determined for each sample run.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Equation</th>
</tr>
</thead>
<tbody>
<tr>
<td>R (mm)</td>
<td>distance (time, @ 2mm/minute) to onset of coagulation</td>
</tr>
<tr>
<td>K (mm)</td>
<td>distance (time, @ 2mm/minute) to a standard clot strength (20 mm amplitude)</td>
</tr>
<tr>
<td>MA (mm)</td>
<td>maximum clot strength (mm amplitude)</td>
</tr>
<tr>
<td>Angle (deg)</td>
<td>proportional to the rate of clot growth</td>
</tr>
</tbody>
</table>

Data from the sample runs were analyzed using the Student’s t-test for independent samples, a statistical test that compares the means of two samples to test the null hypothesis that they are the same.

The test results demonstrate that the 5000 Series TEG® sample measurement performance is equivalent to the 3000 Series analyzer. The analysis shows no statistical significance in all TEG parameters, R, K, MA and Angle, between the 5000 Series and the 3000 Series results at P < 0.05. In addition, the absolute differences between the mean samples (see table below) are all within the instrument accuracy of measurement, which is ±1 unit.

The results are tabulated below, as the means, standard deviations, differences between the means, standard deviations of the differences, t-values, and the 2-tail probability.

<table>
<thead>
<tr>
<th>Parameter Measurement Comparisons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison of means of samples (n=40)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>R (mm)</th>
<th>K (mm)</th>
<th>Angle (deg)</th>
<th>MA (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5000 Series</td>
<td>11.5625 ± 1.178</td>
<td>2.1500 ± 0.379</td>
<td>73.9625 ± 2.382</td>
<td>30.6250 ± 1.036</td>
</tr>
<tr>
<td>(Mean ± SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3000 Series</td>
<td>11.7500 ± 1.276</td>
<td>2.2750 ± 0.423</td>
<td>73.3750 ± 3.061</td>
<td>30.4010 ± 1.261</td>
</tr>
<tr>
<td>(Mean ± SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIFFERENCE</td>
<td>0.1875 ± 0.354</td>
<td>0.1250 ± 0.090</td>
<td>0.5875 ± 0.613</td>
<td>0.2240 ± 1.498</td>
</tr>
<tr>
<td>(Mean ± SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T-VALUE</td>
<td>.68</td>
<td>1.39</td>
<td>.96</td>
<td>.87</td>
</tr>
<tr>
<td>DF</td>
<td>78</td>
<td>78</td>
<td>78</td>
<td>78</td>
</tr>
<tr>
<td>2-TAIL P-VALUE</td>
<td>0.497</td>
<td>.168</td>
<td>0.341</td>
<td>0.388</td>
</tr>
</tbody>
</table>
To demonstrate the TEG® measurement precision using the activators recommended in the TEG® User's Manual (Celite, Tissue factor, Thrombin, DAPTtin, and Kaolin supplied by Haemoscope Corp.), Haemoscope conducted the following evaluation:

Following the steps outlined in the TEG® User’s Manual, 10 cc of blood was drawn from each of five healthy individuals with no known hemostasis problems. Eight (8) TEG measurements were obtained from each blood sample. Using four (4) TEG® analyzers, measurements were run over the course of two (2) days; for Haemoscope’s Kaolin, measurements were run over five (5) days. For each activator, a total of forty (40) measurements were obtained using the activated samples.

Based on the TEG measurement data, the precision of each TEG parameter expressed as a percentage using the coefficient of variation (CV) is as follows for each activator:
Silica Particles (Brand name: Celite; Supplied by Haemoscope Corporation)

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>K</th>
<th>ANG</th>
<th>MA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8.7%</td>
<td>7.6%</td>
<td>2.4%</td>
<td>4.1%</td>
</tr>
</tbody>
</table>

Tissue Factor (Brand name: Hemoliance; Manufacturer: Ortho)

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>K</th>
<th>ANG</th>
<th>MA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13.1%</td>
<td>12.9%</td>
<td>2.3%</td>
<td>3.3%</td>
</tr>
</tbody>
</table>

Thrombin (Brand name: Thrombin Sigma; Manufacturer: Sigma)

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>K</th>
<th>ANG</th>
<th>MA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13.2%</td>
<td>13.4%</td>
<td>3.5%</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

Kaolin / Sulphatide / Phospholipids Blend (Brand name: DAPTTIN; Manufacturer: Immuno)

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>K</th>
<th>ANG</th>
<th>MA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12.7%</td>
<td>17%</td>
<td>2.8%</td>
<td>5.0%</td>
</tr>
</tbody>
</table>

KaolinH / Sulphatide / Phospholipids Blend (Brand name: Kaolin; Supplied by Haemoscope Corporation)

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>K</th>
<th>ANG</th>
<th>MA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>13.4%</td>
<td>4.4%</td>
<td>2.8%</td>
<td>6.3%</td>
</tr>
</tbody>
</table>

These CV values are relatively small in the TEG® parameter comparison with other coagulation instruments, the majority of which are higher.

The “Limitations” section on page 180 of this User Manual describes the sensitivity factors that may affect the measurement capability and operation of the TEG® analyzer. In addition, interference factors that may affect the performance or sensitivity of the TEG® analyzer are listed in the “Limitations” section along with information on ways to mitigate the interference.

Haemoscope provides reference normal ranges in the TEG® software. The reference normal ranges are reproduced in the following table. These normal ranges were derived from data provided by a number of hospitals in the United States.
<table>
<thead>
<tr>
<th>Sample Type</th>
<th>R min</th>
<th>K min</th>
<th>Angle deg</th>
<th>MA mm</th>
<th>G kd/sc</th>
<th>Sample Size*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celite / Kaolin</td>
<td>4 - 8</td>
<td>0 - 4</td>
<td>47 - 74</td>
<td>54 - 72</td>
<td>6.0 - 13.2</td>
<td>132</td>
</tr>
<tr>
<td>Sodium Citrate Celite / Kaolin</td>
<td>2 – 8</td>
<td>1 – 3</td>
<td>55 – 78</td>
<td>51 – 69</td>
<td>4.6 - 10.9</td>
<td>98</td>
</tr>
<tr>
<td>Native</td>
<td>12 – 26</td>
<td>3 – 13</td>
<td>14 – 46</td>
<td>42 – 63</td>
<td>3.2 - 7.1</td>
<td>132</td>
</tr>
<tr>
<td>Sodium Citrate Native</td>
<td>9 – 27</td>
<td>2 – 9</td>
<td>22 – 58</td>
<td>44 – 64</td>
<td>3.6 - 8.5</td>
<td>132</td>
</tr>
<tr>
<td>Tissue Factor</td>
<td>1 – 3</td>
<td>1 – 3</td>
<td>57 – 78</td>
<td>55 – 75</td>
<td>6.0 - 13.0</td>
<td>178</td>
</tr>
<tr>
<td>Sodium Citrate plus TF</td>
<td>0 – 2</td>
<td>0 – 5</td>
<td>52 – 82</td>
<td>46 – 72</td>
<td>2.7 - 12.5</td>
<td>41</td>
</tr>
<tr>
<td>Tissue Factor Kaolin</td>
<td>17 – 38</td>
<td>30 – 118</td>
<td>66 – 82</td>
<td>54 – 72</td>
<td>5.3 - 12.4</td>
<td>86</td>
</tr>
<tr>
<td>Citrated Tissue Factor Kaolin</td>
<td>22 – 44</td>
<td>34 – 138</td>
<td>64 – 80</td>
<td>52 – 71</td>
<td>5.0 - 11.6</td>
<td>89</td>
</tr>
<tr>
<td>Tissue Factor plus Functional Fibrinogen</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>9 – 29</td>
<td>0 - 2.0</td>
<td>72</td>
</tr>
<tr>
<td>Citrated Tissue Factor plus Functional Fibrinogen</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>10 – 25</td>
<td>0.5 - 1.7</td>
<td>72</td>
</tr>
</tbody>
</table>

*Sample sizes range from 41 – 178 depending on participating hospitals.

**Functional Fibrinogen Level Test**

The Correlation of the TEG® Functional Fibrinogen test was assessed following CLSI EP6-P2 guideline.

Citrated whole blood (CWB) samples and platelet poor plasma (PPP) (prepared from corresponding CWB) from three healthy volunteers were used in the study. Donors having known hemostasis factor deficiencies or hemostasis defects, infectious disease, diabetes, phlebitis and other conditions that may inhibit a person from providing blood sample were excluded.

Venous blood was collected into ten 4.5cc siliconized Vacutainer blood tubes (Becton Dickinson, Franklin Lakes, NJ) containing 3.2% trisodium citrate.

500 µl of blood sample was pipetted into the Functional Fibrinogen (FF) reagent vial, re-capped, inverted and swirled gently 5 times. 340 µl of FF activated blood was then pipetted into a cup containing 20 µl of 0.2M CaCl₂.
The samples were run on the TEG® Analyzer at 37 ºC until MA parameters were finalized. The samples were run in duplicate and the \( \text{MA}_\text{pi} \) (MA of FF activated sample) were averaged. The remainder of the blood was used for laboratory determination of fibrinogen level (Clauss Fibrometer Coagulation Timer- BBL Fibrosystem).

To obtain wider range of fibrinogen levels, five serial concentrations with fibrinogen (Clottagen, Laboratoire Francais Du Fractionnement et des Biotechnologies) and four serial dilutions with normosol-citrate-CaCl\(_2\) solution were performed on each of the donors’ citrated whole blood and platelet poor plasma samples. These diluted specimens were subjected to the same sample preparation and TEG® protocol as described above. Fibrinogen levels ranged from 42.6 mg/dl to 1063.5 mg/dl.

It should be noted that the PPP samples were treated with functional fibrinogen reagent to inhibit any residual platelets in the sample. The \( \text{MA}_\text{pi} \) (PPP) therefore is the measurement of the strength of developed clot without the contribution of platelets.

In order to confirm that the Functional Fibrinogen reagent inhibited all the platelets in whole blood samples, a group t-test was run for the \( \text{MA}_\text{pi} \) CWB vs. \( \text{MA}_\text{pi} \) PPP samples. The results of group t-test comparing \( \text{MA}_\text{pi} \) CWB vs. \( \text{MA}_\text{pi} \) PPP showed no statistically significant difference in the MA parameters, results at P value of 0.577.

This indicates that the concentration of platelet inhibitor in the Functional Fibrinogen reagent was great enough to fully inhibit all the platelets and accurately measure the MA due to the fibrinogen contribution. Furthermore, this demonstrates that \( \text{MA}_\text{pi} \) CWB and \( \text{MA}_\text{pi} \) PPP can be used interchangeably to measure functional fibrinogen level.

Linear least squares regression was employed to the combined data (\( \text{MA}_\text{pi} \) CWB and \( \text{MA}_\text{pi} \) PPP) to determine the relationship between TEG® MA\(_\text{pi}\) values and the corresponding fibrinogen levels. A regression line (forced through the origin) was drawn. Statistical significance was accepted when \( p < 0.05 \).

Linear least squares regression analysis indicates that \( \text{MA}_\text{pi} \) is a highly significant predictor of fibrinogen level (\( p \leq 0.001 \)) with a correlation \( r \) value of 0.974, an \( r^2 \) of 0.9489 and a slope of 0.054.

The regression line was forced through the origin because without fibrinogen a clot will not be formed and \( \text{MA}_\text{pi} = 0 \) mm. The high correlation and linearity demonstrates that the \( \text{MA}_\text{pi} \) can be used to estimate the functional fibrinogen level (FLEV).
Also another study showed highly significant correlation ($p < 0.001$) of $\text{MA}_p$ with the Clauss method with a correlation $r$ value of 0.949 and an $r^2$ of 0.9009.

The combination of the two studies (described above) using different fibrinogen level: (1) by serial dilution and (2) by different fibrinogen level as determined by Clauss method demonstrates that the $\text{MA}_p$ can provide a quantitative estimate of the functional Fibrinogen level (FLEV).

**Limitations**

*For in Vitro Diagnostic Use Only*

Users of the TEG® analyzer should be properly trained and should be appropriate medical or other health care professionals.
The TEG® analyzer output is for presentation purposes only, and may vary from time to time; users should use the actual data derived from their own samples and their own established normal ranges to quantify the output tracing as to the degree of abnormality.

Results from the TEG® analyzer should not be the sole basis for a patient diagnosis; results from the TEG® analyzer should be considered along with the patient's clinical condition and other laboratory tests.

Sensitivity factors that may affect the measurement capability and operation of the TEG® analyzer are listed below.

☐ The maximum oscillation of the cup in the TEG® instrument is approximately 5 degrees, as described in the Interference section below. Therefore, the maximum amplitude (MA parameter) cannot be measured beyond 100 mm. It is very rare for human blood to exceed this limit; if it should happen, the diagnosis is obvious—extreme hypercoagulability.

☐ The eTest value of the TEG® instrument determines the zero starting point of the graphical output tracing. Therefore, out of range conditions may prevent the TEG® graph from reaching its maximum amplitude, i.e.; the MA parameter may not reach its maximum value. If this should happen, the software issues a warning.

☐ Non-anticoagulated whole blood samples that are placed on the analyzer later than six minutes after drawing may result in a clotted sample, leading to erroneous results. If this should happen, the software issues a warning.

☐ In addition, the TEG® analyzer has the following environmental specifications that affect testing sensitivity:
  - Operating temperature 15 to 30°C, storage temperature –30 to 50°C
  - No solar radiation
  - Indoor use
  - Mains supply fluctuations not to exceed ±10% of the nominal voltage
  - Maximum relative humidity 80%
  - Over-voltage Category II
  - Pollution degree 2

Interference factors that may affect the performance or sensitivity of the TEG® analyzer are listed below along with information on ways to mitigate the interference:

---

**Sensitivity factors**

- The maximum oscillation of the cup in the TEG® instrument is approximately 5 degrees, as described in the Interference section below. Therefore, the maximum amplitude (MA parameter) cannot be measured beyond 100 mm. It is very rare for human blood to exceed this limit; if it should happen, the diagnosis is obvious—extreme hypercoagulability.

- The eTest value of the TEG® instrument determines the zero starting point of the graphical output tracing. Therefore, out of range conditions may prevent the TEG® graph from reaching its maximum amplitude, i.e.; the MA parameter may not reach its maximum value. If this should happen, the software issues a warning.

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  - No solar radiation
  - Indoor use
  - Mains supply fluctuations not to exceed ±10% of the nominal voltage
  - Maximum relative humidity 80%
  - Over-voltage Category II
  - Pollution degree 2

---

**Interference factors**

- The maximum oscillation of the cup in the TEG® instrument is approximately 5 degrees, as described in the Interference section below. Therefore, the maximum amplitude (MA parameter) cannot be measured beyond 100 mm. It is very rare for human blood to exceed this limit; if it should happen, the diagnosis is obvious—extreme hypercoagulability.

- The eTest value of the TEG® instrument determines the zero starting point of the graphical output tracing. Therefore, out of range conditions may prevent the TEG® graph from reaching its maximum amplitude, i.e.; the MA parameter may not reach its maximum value. If this should happen, the software issues a warning.

- Non-anticoagulated whole blood samples that are placed on the analyzer later than six minutes after drawing may result in a clotted sample, leading to erroneous results. If this should happen, the software issues a warning.

- In addition, the TEG® analyzer has the following environmental specifications that affect testing sensitivity:
  - Operating temperature 15 to 30°C, storage temperature –30 to 50°C
  - No solar radiation
  - Indoor use
  - Mains supply fluctuations not to exceed ±10% of the nominal voltage
  - Maximum relative humidity 80%
  - Over-voltage Category II
  - Pollution degree 2
The moving part of the TEG® analyzer is a cylindrical cup, which oscillates very slowly through an angle of approximately 5 degrees. Therefore:

- The TEG® instrument has to be level. A leveling bubble and leveling feet are built into the instrument.
- The TEG® instrument is sensitive to vibration. We recommend that the TEG® analyzer be set up such that vibrations and jolting are avoided.

The analog signal generated by the oscillating pin is converted (by an analog to digital board) at the rate of 10 samples per second. The digitized data is continuously transmitted to the software via a serial port (either COM1 or COM2). Therefore, any communication interference with these ports should be eliminated, and all sleep modes and screen and power savers should be disabled.

The TEG® analysis is very sensitive to anticoagulants, especially heparin. In the clinical setting, to prevent blood activation, most of the tubes (such as catheter lines) and extra-corporeal surfaces are coated with heparin, which occasionally is released into the blood stream in very small quantities, and results in heparin-contaminated samples being analyzed by the TEG® instrument. Therefore, it is imperative to use heparinase (such as lyophilized heparinase cups) to eliminate heparin contamination.

The TEG® instrument is a bedside whole blood analyzer. The standard mode of operation is drawing a blood sample that is immediately placed in the TEG® cup for analysis without being anti-coagulated. Because a clotting process begins as soon as the blood is drawn, a constant time interval for sample application onto the analyzer (e.g., four minutes) should be used to eliminate biases due to different time intervals in placing the blood in the TEG® cup.
Make sure you have the following equipment available before proceeding:

- Thrombelastograph® (TEG®) 5000 series analyzer
- Analog/Digital Interface Box
- Cables (RS232 or DB9)
- Computer with printer as specified in Appendix A
- CD(s) containing the TEG® Analytical Software
- Trimmer adjustment tool (provided by Haemoscope Corp.)
Positioning the Analyzer

The analyzer should be set up such that vibrations and jolting are avoided, and where the power cord is not in danger of being disconnected from either the analyzer or wall outlet. Room temperature should not exceed 30°C. The interface box contains a board that converts the analog signals from the analyzer to digital signals. The interface box must be connected to the analyzer and the computer. The interface box should be set up such that the cables will not become kinked or bent.

1. Using the female-female DB9 cable, connect one end to the serial port connector on the computer (#1 Fig. B1) and the other end to the connector labeled “Computer” on the interface box. (#2 Fig. B1).

2. Using a 9-pin male-male DB-9 cable, connect one end to the back panel of the analyzer (#4 Fig. B1) and the other end to the TEG1 receptacle of the A/D interface box (#3 Fig. B1). If you have only one analyzer, it must always be connected to receptacle TEG1 on the interface box, since the power for the interface is derived from this connection.

3. If you have more than one analyzer, one of them must be connected to receptacle TEG1. For multiple analyzers, the position of the cable connection on the interface box determines the assignment of channel numbers for the analyzers. The analyzer connected to receptacle TEG1 of the interface box will be identified by the computer as channel 1 (left channel) and channel 2 (right channel). The analyzer connected to receptacle TEG2 of the interface box will be identified by the computer as channel 3 (left channel) and channel 4 (right channel) and so on for positions TEG3 through TEG4 of the interface box.

4. Turn on the analyzer connected to receptacle TEG1. If the connection is correct, the light on the interface box will go on.
The TEG® analyzer must be leveled before use.

Use the procedures detailed on page 126 to level the analyzer.

Software installation and user configuration is described in the separate document named Site Administrator Guide and should be performed by the site administrator.

By default, a Site Administrator user is automatically set up when installing the software. The installation guide describes how to log in as Site Administrator and how to create new users.

☐ The minimum configuration to be able to run samples is to "activate" channels that are attached to the computer. The Maintenance screen provides a tab that activates the channels. The Maintenance screen is accessed from the Main toolbar using the Options entry.

1. This displays the Maintenance screen with the Setup tab.

2. The second column stores the serial number of the analyzer for that channel. Machine serial numbers are required. The machine serial numbers are stored in pairs, so that whatever you enter for one channel is automatically copied to the other channel for that analyzer. For example, when the machine serial number for channel 1 is entered, it is automatically copied to channel 2. You can also optionally enter channel serial numbers into
for channel 1 is entered, it is automatically copied to channel 2. You can also optionally enter channel serial numbers into the third column. Pending samples will only appear in the TEG screen for those channels check marked in this screen.

☐ Run eTest

☐ Perform the temperature test as described in the separate document named the TEG Service Manual.

The TEG® 5000 Series System is portable and does not require any installation for proper operation, although selection of a suitable location for setup and operation is important. Normal equipment setup procedures are described elsewhere in this User Manual. After delivery to the responsible body (responsible for the use and maintenance of the TEG® 5000 Series analyzer), the TEG® 5000 Series may be transported to the final setup location by any reasonable and safe means. It is required that any person using the TEG® 5000 Series must be properly trained in the clinical use of the equipment prior to use.

Precautions must be taken by the responsible body regarding the elimination or reduction of hazards involved with removing the TEG® 5000 Series analyzer from its point of use, transporting the TEG® 5000 Series from one place to another, or disposing of the TEG® 5000 Series. Although the TEG® 5000 Series does not present significant biohazard risk in itself, the unit is used to analyze human blood, so care must be taken to properly clean and disinfect the equipment as appropriate.

The TEG® 5000 Series is to be operated by qualified personnel only. Read all instructions, precautionary information and specifications prior to use. If this equipment is used in a manner not specified by Haemoscope, protections provided by the equipment may be impaired.

Use only Haemoscope accessories with the TEG® 5000 Series. Other manufacturer’s accessories may cause improper performance. Do not use malfunctioning equipment. Have the unit repaired by Haemoscope or an authorized service representative.

Symbols

CAUTION: BIOHAZARD
Turn off and lock out power before servicing.

In vitro type medical device
Functional fibrinogen level (FLEV) is a measurement of the strength or stiffness of the developed clot without the contribution of platelets. The MA parameter in the TEG® analyzer measures the strength of the fibrin / platelet bonding via GPIIb/IIIa receptors. MA with high concentrations of platelet inhibitor agents (MAF) measures fibrin contribution to MA, and MA – MAF (MAP) then measures the contribution of platelets to MA. Some of the GPIIb/IIIa receptor antagonists currently in use include abciximab (ReoPro®), etifibatide (Integrilin®), and tirofiban (Aggrastat®).

GPIIb/IIIa receptor inhibiting drugs are now being used extensively in humans undergoing elective angioplasty who are at high risk of abrupt vessel closure post surgery. Since all platelet-fibrin(ogen) interaction is mediated via the platelet integrin GPIIb/IIIa receptor, they inhibit platelet-fibrin(ogen) interaction by binding to these receptors. The TEG® MA parameter measures the strength of the fibrin and platelet bonding via GPIIb/IIIa, and, therefore, when a GPIIb/IIIa inhibitor is added to the TEG® sample, the MA is reduced proportionally to the concentration of the inhibitor added.

Samples treated with GPIIb/IIIa inhibiting agents receive special handling in the program. For consistency, these samples are identified in the software as FF sample type, and the drug can be any of the GPIIb/IIIa platelet antagonists.

When you display the tracing of an active FF sample or an FF sample stored in the database, the program displays the value of FLEV (or functional fibrinogen level) in the center of the screen at the top, replacing the sample description. This is an estimated value based on the value of the MA parameter. If there is no value shown for MA (not even an interim value), there will be no value displayed under the FLEV heading. Once MA is defined, even on an interim basis, FLEV is defined.

When you select exactly two samples to be displayed in Multiple Tracing mode (whether they are active channels or from the database), if one of the samples is an FF sample, then additional data appears in the center of the screen at the top, replacing the sample description.
These values are:

MA_p - The value of MA due to platelet contractility. It is defined as the absolute difference between the MA value of the FF sample and the MA value of the other sample without GPIIb/IIIa inhibitor.

ANG_p - The value of angle due to platelets. It is defined as the absolute difference between the angle value of the FF sample and the angle value of the other sample without GPIIb/IIIa inhibitor.

FLEV - The functional fibrinogen level is computed using the MA value of the FF sample.

In Interpretation

When you interpret the results of an FF sample or of a sample that has been paired (via Multiple Tracing) with an FF sample, you have three additional parameters to use in the interpretation of TEG® results. They are:

MA_p - MA value due to platelets (see above)

ANG_p - Angle value due to platelets (see above)

FLEV - Estimated functional fibrinogen level (as defined above)

**Note:** These parameters are generated by the Multiple Tracing screen as described earlier. You must run the Multiple Tracing screen on the two samples (one of which is an FF sample) in order to have the FF parameters available for interpretation.

As described in many locations in this manual, platelets play a critical role in mediating ischemic complications resulting in stroke and myocardial infarction. Platelet inhibiting drugs can result in a dramatic reduction in the risk of death, myocardial infarction, or other ischemic events such as re-occlusion after percutaneous transluminal coronary angioplasty (PTCA) or intra-arterial thrombolytic therapy (IATT).

Anti-platelet agents that directly inhibit GPIIb/IIIa receptors include drugs such as the abciximab (ReoPro®), tirofiban (Aggrastat®), and eptifibatide (Integrillin®). Clopidogrel (Plavix®) and ticlopidine (Ticlid®) inhibit the ADP receptor, and aspirin inhibits the activation of the platelet thromboxane A2 receptor. Administration of excessive amounts of anti-platelet agents could lead to life-threatening bleeding. Because of the narrow risk/therapeutic ratio with this class of drugs, a precise estimate of platelet function inhibition in a patient treated with platelet inhibiting drugs is very important for the monitoring of drug delivery.

The TEG MA parameter provides an overall estimate of platelet-fibrin GPIIb/IIIa bonding, which is used, for example, to guide post-operative blood platelet or fibrinogen replacement therapy. When considering only platelets and fibrin, an abnormally low MA implies that there is an abnormality in func-
tional platelets (i.e., low platelet number or functional defect) and/or an abnormality in fibrinogen content in the blood. However, if fibrinogen level and platelet number are constant, any change in MA would reflect changes in platelet function (aggregation). Therefore, by testing the same blood sample two ways, one with an anti-platelet agent and one without, the difference between the two MAs reflects the extent of platelet inhibition by the anti-platelet agent.

The PlateletMapping Assay measures the effect of platelet-inhibiting drugs using two blood modifiers. One modifier uses ADP on blood treated with a thrombin inhibitor (e.g., heparin) as a part of the assay, to activate the platelets that have not been inhibited by platelet ADP receptor-inhibiting drugs such as clopidogrel and/or GPIIb/IIIa receptor-inhibiting drugs such as abciximab, tirofiban, or eptifibatide. The extent of platelet inhibition caused by these anti-platelet drugs is reflected in a reduction in the TEG MA value (MA_{ADP}).

The second modifier uses arachidonic acid (AA) on blood treated with a thrombin inhibitor (e.g., heparin) as part of the assay, to activate the platelets that have not been inhibited by platelet thromboxane A2 receptor-inhibiting drugs such as aspirin and/or GPIIb/IIIa receptor-inhibiting drugs such as abciximab, tirofiban, or eptifibatide. The extent of platelet inhibition caused by these anti-platelet drugs is reflected in a reduction in the TEG MA values (MA_{AA}).

For ease of use, the TEG software calculates and displays the % platelet inhibition when the appropriate samples are selected and viewed in the Multi sample display screen, in a similar fashion as described above for functional fibrinogen level, and on page 53 under Platelet mapping.

See the PlateletMapping Instructions for Use (Product Insert) for specific instructions on how to run the assay.
Note: The TEG® analyzer should never be loaded while the lever is in the Test position

<table>
<thead>
<tr>
<th>Login</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>The password does not work.</td>
<td>Password is case sensitive.</td>
<td>Check that the keyboard is not set to 'caps lock'.</td>
</tr>
<tr>
<td></td>
<td>New password has been entered.</td>
<td>Contact your Site Administrator for the new password.</td>
</tr>
<tr>
<td>Error message reading “This file is either opened exclusively by another user or is ‘Read Only’…” followed by second error “The config file could not be opened…”</td>
<td>cfg.set on user’s computer is read only.</td>
<td>In Windows Explorer select cfg.set file in same directory as V4 executable, right click on it, select “Properties” and look for “Read Only” attribute on General tab; make sure this is NOT checked.</td>
</tr>
<tr>
<td>When Patient database is selected “This file is either opened exclusively by another user or is ‘Read Only’…” appears.</td>
<td>Patient database is read only.</td>
<td>In Windows Explorer select database you want to open, right click on it, select “Properties” and look for “Read Only” attribute on General tab; make sure this is NOT checked.</td>
</tr>
<tr>
<td></td>
<td>Trying to run the database off of a CD.</td>
<td>If the database is being read off the CD, copy the database to the desktop. Then in Windows Explorer select database you want to open, right click on it, select “Properties” and look for “Read Only” attribute on General tab; make sure this is NOT checked.</td>
</tr>
<tr>
<td>At login Patient database name message is issued “does not exist”.</td>
<td>Database unavailable</td>
<td>On a network, make sure network connections are secure and network is running properly; if a local database, type the full path instead of just database name.</td>
</tr>
</tbody>
</table>
## Login

<table>
<thead>
<tr>
<th>Issue</th>
<th>Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannot access a QC database.</td>
<td>A QC database can only be entered if running the TEG® Enabled version of the software, it cannot be accessed on Remote software.</td>
<td>Access the database on a computer where the TEG® enabled software is installed.</td>
</tr>
<tr>
<td>Cannot create a new QC database.</td>
<td>A QC database can only be created within the TEG® Enabled version of the software.</td>
<td>Access the database on a computer where the TEG® enabled software is installed.</td>
</tr>
<tr>
<td>Unable to find the database I am looking for using the “Locate” button.</td>
<td>The “Find” process only works if the database is on the drive selected at the top of the “Find” screen. If the database is on a different drive, or over the network, the “Find” function will not locate the database.</td>
<td>Select another drive in the disk drive input box.</td>
</tr>
<tr>
<td>Entered the program and selected user, but personal settings are not showing.</td>
<td>Selected user and cursor is still in the User field (did not click on anything else).</td>
<td>Click on something else, or press Tab to get your default settings displayed in the Login screen. Press Enter and enter the program with your default settings.</td>
</tr>
<tr>
<td>Upon entering the program, and selecting the user and hitting Tab, the default Patients (or QC) database did not get loaded as the database to enter.</td>
<td>Modified the database field.</td>
<td>If you have already modified the database text field (for either database) before you select your user, then your defaults will not over write the databases you manually entered. You would have to either manually select your databases, or exit the program and enter again, and select your user without modifying the fields on the Login screen.</td>
</tr>
<tr>
<td>When attempting to get into the TEG® screen, a message pops up saying that the COM port is in use, or does not exist. A COM port does exist, and there is no other instance of the TEG® software running, and the analyzer has already re-started. What is using the COM port?</td>
<td>Another program or driver is using the COM port, e.g. touch screen, palm pilot. The TEG® software will give an error even if they are not connected.</td>
<td>Check if any new programs or drivers have been loaded since the last time the program was run. Any software or driver that uses a COM port could potentially cause this problem. Either use a different port for the TEG® software, use a different port for the software causing the problem, or un-install the problem software.</td>
</tr>
<tr>
<td>A 3.0 database has been accidentally converted to version 4.</td>
<td>When a 3.0 database is opened by version 4, it is automatically converted.</td>
<td>A 3.0 backup is automatically created when a database is converted. This can be found in the following directory: by default C:\CTEG in a directory called BackupV3.</td>
</tr>
<tr>
<td>Unable to login as the Site administrator because the Site Administrator is unavailable.</td>
<td>Site administrator password unknown</td>
<td>Call your rep. You could just over write the cfg.set file that is in the same folder as the executable, with cfg.set on the installation CD. If you do that, the Site Administrator’s password will revert to the default. WARNING: You will lose all of your current user setting.</td>
</tr>
</tbody>
</table>
## Troubleshooting

### Maintenance

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>When checking eTest, the “Channel not at equilibrium” message was issued.</td>
<td>Data processing.</td>
<td>Give the software a little more time to process the data, or click on eTest again.</td>
</tr>
<tr>
<td></td>
<td>Analyzer can be sensitive to external vibrations.</td>
<td>Check that the analyzer is on a secure surface that is not being exposed to any vibrations.</td>
</tr>
<tr>
<td>When checking eTest the software issues the message, “eTest off center”.</td>
<td>The lever is in load.</td>
<td>Move the lever to “Test” and click on the eTest button again.</td>
</tr>
<tr>
<td></td>
<td>The analyzer is not level.</td>
<td>Use the bubble level at the top of the analyzer to ensure the analyzer is level.</td>
</tr>
<tr>
<td></td>
<td>The eTest is off center.</td>
<td>Adjust the corresponding “BASE” potentiometer in the back of the analyzer.</td>
</tr>
<tr>
<td>A “eTest out of range” message came up on the screen while running samples.</td>
<td>Possible eTest out of range.</td>
<td>End the sample and run eTest.</td>
</tr>
<tr>
<td></td>
<td>Started the wrong channel.</td>
<td>End the sample on the channel you accidentally started, and re-run the sample.</td>
</tr>
<tr>
<td>Once the baseline was adjusted the message did not update to reflect the new numbers in the MIN and MAX.</td>
<td>The message does not update to reflect any change in the status of the eTest.</td>
<td>Highlight the channel you are using and click on eTest again.</td>
</tr>
<tr>
<td>eTest results are not saved.</td>
<td>The ‘Service mode’ selection is checked</td>
<td>In the maintenance screen, un-check the service mode.</td>
</tr>
<tr>
<td>An eTest result is not showing up on the report.</td>
<td>The ‘Service mode’ selection is checked</td>
<td>In the maintenance screen, un-check the service mode box.</td>
</tr>
<tr>
<td></td>
<td>Separate pages for separate days on the report.</td>
<td>The data for each day is started on a separate page. If you are looking at the data for two days, there will be at least two pages, even if each page only has one line of data.</td>
</tr>
<tr>
<td>Upon entering the Maintenance screen, the serial number for the analyzer being tested is not saved from the previous entry.</td>
<td>Service mode box is checked or final results have not been saved.</td>
<td>Uncheck Service mode and run a maintenance function, waiting for a final message.</td>
</tr>
</tbody>
</table>
## Loading the cups and pins

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>The pin sometimes slips down into the cup.</td>
<td>The pusher is not being pushed fully.</td>
<td>When loading the cup and pin, push the pin firmly into place using the plastic pusher located at the bottom of the carrier. Counterbalance the analyzer by holding your other hand on the top while pushing the pin. Make sure that the pin is correctly loaded by checking that the bottom tip of the spindle is touching the inside bottom of the disposable pin.</td>
</tr>
<tr>
<td>The cup isn’t flush with the carrier.</td>
<td>The cup has not been reseated after the pin is pushed up.</td>
<td>Press the cup into the carrier being sure not to touch the inside of the cup and that the carrier is not being pushed against the bottom plate.</td>
</tr>
</tbody>
</table>

## Biological Controls

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>The biological control samples are missing.</td>
<td>The database was closed and all the QC samples were automatically transferred to the QC database.</td>
<td>Click on QC in the main menu and select ‘GO TO’.</td>
</tr>
<tr>
<td>All the parameters passed but one.</td>
<td></td>
<td>For the TEG to successfully pass the QC test, three of the four parameters must be within range.</td>
</tr>
<tr>
<td>A lot number was created but the software says the lot number does not exist.</td>
<td>There are two different QC databases being used and each database needs the lot numbers inputted separately.</td>
<td>Create the lot number for every QC database you use.</td>
</tr>
<tr>
<td>When trying to enter a new lot number the screen to enter a new patient pops up.</td>
<td>The sample type was not set to L1 or L2.</td>
<td>Set the sample type before you type in the lot number.</td>
</tr>
<tr>
<td>One channel's R is elongated, and the angle is small, but the K and MA are in range.</td>
<td>The temperature in the carrier may be too low.</td>
<td>Check to make sure both carriers are set to 37.0 degrees. Also, check that the ribbon cable located between the carrier and the analyzer is tight. Clean the carrier and ribbon cable with alcohol. Make sure the analyzer is not in front of a window or by an air duct. If the channel is still giving the same results contact your local service rep.</td>
</tr>
</tbody>
</table>
### Biological Controls

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>MA in one channel is consistently out of range.</td>
<td>The channel is out of calibration.</td>
<td>Contact your local service rep.</td>
</tr>
<tr>
<td>The R in one channel is very short, and the MA is very large, while the MA in the other channel is very small.</td>
<td>Analyzer is not level.</td>
<td>Use the bubble level at the top of the analyzer to ensure the analyzer is level.</td>
</tr>
<tr>
<td>Both channels have more than one parameter out of range.</td>
<td>Biological control vial questionable.</td>
<td>Reconstitute new vial and re-run the control.</td>
</tr>
<tr>
<td>R and K values are out of range according to the insert, but not according to the software</td>
<td>Units reported in the software are in mm</td>
<td>Conversion is 2mm=1 minute</td>
</tr>
</tbody>
</table>

### Unexpected tracing results

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight line tracings.</td>
<td>There is no communication between the analyzer and the computer.</td>
<td>Turn on the TEG® Analyzer that is plugged into the serial port labeled TEG1 on the A/D box. Be sure the power light on the A/D box turns on.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tighten any loose connections.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Go into system set-up and choose the correct COM port.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Turn on the motor.</td>
</tr>
<tr>
<td></td>
<td>The sample was not prepared properly.</td>
<td>If heparin is suspected, use a blue heparinase cup.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Add 20 ul calcium chloride to a sodium citrate sample.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Add 20 ul calcium chloride to a biological control sample.</td>
</tr>
</tbody>
</table>
### Troubleshooting

<table>
<thead>
<tr>
<th>Issue</th>
<th>Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unusual dips and spikes in tracings.</td>
<td>Cups and pins may not have been loaded properly.</td>
<td>Re-run the sample.</td>
</tr>
<tr>
<td>Data from the A/D box was interrupted.</td>
<td>Make sure all cable connections are secure and cables are not bent or kinked.</td>
<td>Compact the database.</td>
</tr>
<tr>
<td>Unstable environment/vibrations.</td>
<td>Make sure the analyzer is in a low vibration environment.</td>
<td>Turn on the TEG® Analyzer that is plugged into the serial port labeled TEG1 on the A/D box. Be sure the power light on the A/D box turns on.</td>
</tr>
</tbody>
</table>

### Running Samples

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to start samples in the Main screen.</td>
<td>Must be in the TEG® screen to start samples.</td>
<td>Click on the “Teg” button on the local toolbar to get to the TEG screen.</td>
</tr>
<tr>
<td>Unable to get to the TEG screen.</td>
<td>Using the remote version of the software.</td>
<td>Must be in the TEG Enabled version to get to the TEG screen.</td>
</tr>
<tr>
<td>Unable to change information for active samples.</td>
<td>Location of the sample.</td>
<td>If the sample was not started on that analyzer, data cannot be modified.</td>
</tr>
<tr>
<td>Upon terminating samples, the “Select a patient” screen comes up.</td>
<td>Sample was terminated without a patient selected.</td>
<td>The “Done” button assigns the selected patient to the sample. The “Create” button brings up the patient creation screen. Clicking “Ignore” creates a new patient with the current time and date as the name, and assigns it to the terminated sample. The “Cancel” button cancels the termination of the sample.</td>
</tr>
</tbody>
</table>
## Running Samples

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>When running samples, the “Select a patient” screen will come up ...</td>
<td>Automatic termination.</td>
<td>If your samples are set to terminate automatically, and the criteria is met, the dialog box will come up if the sample does not have a patient defined for it yet. If you click “Cancel”, the termination is cancelled, and the sample keeps running. When the next data point comes in, the program realizes the sample is supposed to terminate, and brings the dialog box back up. To stop the cycle, do not click “Cancel”, but choose a patient, or click “Ignore”, and change the patient for that sample later.</td>
</tr>
<tr>
<td>The analyzer was bumped, and a spike appeared during the tracing. The spike has disappeared.</td>
<td>Optimization</td>
<td>The last minute's worth of data is constantly being filtered and optimized. This allows some artifacts to be removed from the tracing.</td>
</tr>
<tr>
<td>A spike was caused right at the end of the tracing and did not get smoothed.</td>
<td>Filtering process needs time</td>
<td>If a spike occurs at the end of a sample, then you need to let the filtered data catch up. If you exit the program immediately, start another sample right away, or do an eTest check on that sample right after the termination, the filtered data will not be able to be collected, and the spike would not get smoothed.</td>
</tr>
<tr>
<td>A spike occurred in the tracing and did not get smoothed. The sample ran for ten minutes after the spike.</td>
<td>Filtering process only works on certain spikes.</td>
<td>If the disturbance is too much, or for too long, it cannot be smoothed out.</td>
</tr>
<tr>
<td>A sample was run from the TEG screen and the “Done” button was clicked. Sample is not showing up on the Main screen.</td>
<td>Filter active</td>
<td>Either adjust the filter to include this tracing or de-activate the sample.</td>
</tr>
<tr>
<td>After entering the patient name for a sample, changed the sample type, and get a message saying that “this Lot number does not exist”, and a prompt is displayed asking if I want to create it. The patient is in the database, since there are other samples for him.</td>
<td>Database retrieval.</td>
<td>If you change the sample type to L1 or L2, the names are retrieved from the QC database, instead of the Patients database. So, while you selected a patient that exists in the Patients database, it does not exist in the QC database, and so you must create that lot number.</td>
</tr>
<tr>
<td>No value is displayed for CI</td>
<td>K value is undefined</td>
<td>MA &lt; 20mm, leaving K undefined, and CI cannot be calculated with undefined values.</td>
</tr>
</tbody>
</table>
## Temperature controller

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>“BAD” or a high temperature is flashing.</td>
<td>Carrier is not getting information from the temperature controller. Or there is no communication between the carrier and the temperature controller.</td>
<td>Check that the ribbon cable located between the carrier and the analyzer is tight. Clean the carrier and ribbon cable with alcohol. Call your local service rep.</td>
</tr>
<tr>
<td>Temperature stays at room temperature and will not heat up to 37.0 degrees.</td>
<td>Carrier is not getting information from the temperature controller. Or there is no communication between the carrier and the temperature controller.</td>
<td>Check that the ribbon cable located between the carrier and the analyzer is tight. Clean the carrier and ribbon cable with alcohol. Call your local service rep.</td>
</tr>
<tr>
<td>Temperature is not at 37.0 degrees ± 0.5.</td>
<td>Temperature set point was changed.</td>
<td>Reset set point to 37.0 degrees.</td>
</tr>
</tbody>
</table>

## Normal ranges

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannot see the “normal ranges” in the main screen.</td>
<td>The main screen does not display the normal ranges.</td>
<td>Select the desired tracing, then click on the “Max” button.</td>
</tr>
<tr>
<td>The “normal ranges” are not in the “Max” screen.</td>
<td>A sample type was not entered for that channel.</td>
<td>Select the desired sample type for that channel.</td>
</tr>
<tr>
<td></td>
<td>The sample type you are using does not have normal ranges programmed into the software.</td>
<td>Input normal ranges.</td>
</tr>
</tbody>
</table>

## Ejecting the cup and pin

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>The pin will not come off the skewer.</td>
<td></td>
<td>Press the lever down into the “eject” position.</td>
</tr>
<tr>
<td>The cup will not come easily out of the carrier.</td>
<td></td>
<td>Push the carrier firmly against the tray, then lift the cup out of the carrier.</td>
</tr>
</tbody>
</table>
### Remote Access

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>When viewing a database over the network, the following error was issued: &quot;The file is currently locked. Click 'OK' to try again, or 'Cancel' to terminate the program. If the retry is successful, the display will reset to its original settings.&quot;</td>
<td>Another user is trying to access the same record at the same time.</td>
<td>Click ‘OK’ to try again or wait until the other user is done.</td>
</tr>
<tr>
<td>The database cannot be accessed over the network.</td>
<td>Database drive is not shared and accessible.</td>
<td>Contact your IT department.</td>
</tr>
<tr>
<td>Unable to run samples in the Remote version of the program.</td>
<td>Samples cannot be run in the remote version of the software.</td>
<td>Install the TEG enabled version of the software.</td>
</tr>
<tr>
<td>When accessing a database over the network, the screen flickers every so often.</td>
<td>Database refresh</td>
<td>When accessing a database over the network, the program refreshes the data about every 30 seconds if a change was made to the database. If a sample is being run in that database, the program will refresh every thirty seconds. If no sample is being run, then the program will refresh when a change is made. The flickering is the program refreshing.</td>
</tr>
<tr>
<td>When accessing a database over the network, unable to change the sample description of any active samples.</td>
<td>Data protection.</td>
<td>Active samples cannot be modified except from the computer running the samples.</td>
</tr>
<tr>
<td>When viewing a database, a sample disappeared when the program refreshed.</td>
<td>Data propagation.</td>
<td>This is probably due to another user deleting the sample.</td>
</tr>
<tr>
<td>When trying to print, a message popped up saying that &quot;This database has too many users printing on it, or is damaged.&quot;</td>
<td>This means that either 1) too many people are printing on that database at one time (the maximum is 10), or 2) the database did not get properly cleaned up after subsequent prints.</td>
<td>Wait until everyone else is done printing, or, if you are sure that no one else is printing (or in the print preview), compact the database you are trying to print on. This is done from the “File” menu. You cannot compact a database that is open, even if you are the only one viewing it. You would need to exit the database, and then compact the desired database.</td>
</tr>
<tr>
<td>Someone changed the patient name of a sample over the network, but when the program refreshed, the sample still had the old name.</td>
<td>Data protection.</td>
<td>Wait until the other user moves focus to another field.</td>
</tr>
<tr>
<td></td>
<td>Filter active</td>
<td>Change any filter criteria to include the sample (e.g., if the sample is terminated, undo the Active filter).</td>
</tr>
</tbody>
</table>
### Appendix D: Troubleshooting

#### Printing

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>When trying to print, the following error occurs: “This database has too many users printing on it, or is damaged.”</td>
<td>Database clutter.</td>
<td>Run the Compact utility on the specified database.</td>
</tr>
<tr>
<td>When trying to print, a message occurs saying that a printer needs to be loaded on the computer.</td>
<td>No default printer is set.</td>
<td>Contact your IT department.</td>
</tr>
<tr>
<td>When trying to do a Quick Print the Print button is disabled.</td>
<td>No tracing is selected.</td>
<td>Highlight the tracing you would like to print, and click on the Quick Print button.</td>
</tr>
<tr>
<td></td>
<td>There are multiple tracings displayed. In the Multi screen, the Print button is disabled.</td>
<td>Press the F6 key, and that will automatically send the tracing to the default printer.</td>
</tr>
<tr>
<td>Every time when doing a Quick Print, a printer needs to be selected, even though the default printer is always selected.</td>
<td>This is according to specification.</td>
<td>Press the F6 key instead of clicking on the Quick Print button.</td>
</tr>
<tr>
<td>All pages of report print, instead of current page</td>
<td>No subset specified</td>
<td>When choosing the printer to use, you can also select the page subset to print.</td>
</tr>
<tr>
<td>The Maintenance report does not display the results from today.</td>
<td>The data was not saved because the Service mode box was checked.</td>
<td>Run the maintenance again.</td>
</tr>
<tr>
<td></td>
<td>Filter enabled.</td>
<td>When choosing which data would be displayed, you chose to filter by date, and excluded today.</td>
</tr>
<tr>
<td></td>
<td>The data is not on the first page.</td>
<td>Scroll to a different page.</td>
</tr>
<tr>
<td>Values are missing from the printed report.</td>
<td>Default print options settings may need to be adjusted.</td>
<td>Only the top ten tests (selected in user profile setup for individual users, and in system setup for the Site Administrator) will print. To show more tests in the printed report select the “All tests” option when choosing the print options.</td>
</tr>
</tbody>
</table>
## Printing

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>When printing, an error occurs that a table cannot be locked because another user is accessing it, and the database compacting utility needs to be run.</td>
<td>If the program or computer crashed in the process of generating the print preview, it is possible that the database was never released.</td>
<td>Exit the program, and make sure that no one else is accessing that database. Then, use Windows Explorer to go to the folder that holds the database you were trying to print from (probably C:\CTEG). Look for a file that has the same name as the database you were accessing, but ends in &quot;ldb&quot; (for example: Patients.ldb). Select and delete the .ldb file. <strong>MAKE SURE YOU DO NOT DELETE ANY .TEG OR .QC FILES!</strong> Enter the program in a database other than the one you were trying to print from, and run the compact utility on the database you were trying to print from.</td>
</tr>
<tr>
<td>Nothing happens when trying to print.</td>
<td>Network status and permissions</td>
<td>If trying to print over the network, you must make sure that the network is up, and that you have the right permissions to print on the hosting computer.</td>
</tr>
<tr>
<td>When you try to print a tracing by pressing F6, more than one copy prints.</td>
<td>The default copies property of the printer is set to more than 1.</td>
<td>To change the copies property of your printer, contact your IT department.</td>
</tr>
</tbody>
</table>

## Database

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>When you open a version 3 database with version 4, no procedure name is added to the patient name for the case.</td>
<td>The automatic conversion of databases from version 3 to version 4 does not insert a procedure name. New cases created in version 4 have the date and time automatically inserted if you do not enter a procedure. Any converted cases have the date and time automatically inserted when you edit their data, unless you enter a procedure name.</td>
<td>None. Known issue.</td>
</tr>
</tbody>
</table>
# Database

<table>
<thead>
<tr>
<th>Issue</th>
<th>Possible Cause</th>
<th>Possible Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>When entering a database, you get an error “Object or With Block variable not set”</td>
<td>Possible corruption</td>
<td>Exit the patient database, make a copy/backup of the original problem database, and then compact the compacted database, and restore the copy/backup made. Then, create a new database, and merge in the problem database. Repeat the process for the QC database.</td>
</tr>
<tr>
<td>You get the error “Search key not found”</td>
<td>Possible corruption</td>
<td>Exit the patient database, make a copy/backup of the problem database, and then compact the original problem database. Enter the database and check to make sure that no data was lost. If data was lost, delete the compacted database, and restore the copy/backup made. Then, create a new database, and merge in the problem database. Now repeat the process for the QC database.</td>
</tr>
<tr>
<td>While scrolling down or up, the same patient name stays in the top sample's slot.</td>
<td>Possible corruption</td>
<td>Exit the patient database, make a copy/backup of the problem database, and then compact the original problem database. Enter the database and check to make sure that no data was lost. If data was lost, delete the compacted database, and restore the copy/backup made. Then, create a new database, and merge in the problem database. Now repeat the process for the QC database.</td>
</tr>
<tr>
<td>Tracings or test values disappear from a database</td>
<td>Possible corruption</td>
<td>Exit the patient database, make a copy/backup of the problem database, and then compact the original problem database. Enter the database and check to make sure that no data was lost. If data was lost, delete the compacted database, and restore the copy/backup made. Then, create a new database, and merge in the problem database. Now repeat the process for the QC database.</td>
</tr>
</tbody>
</table>
| Someone deleted samples                                               | Restore an earlier backup of the database | \n
Appendix D: Troubleshooting
## Database

<table>
<thead>
<tr>
<th>Error Description</th>
<th>Possible Cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Get the error “Object or With Block variable not set” when scrolling.</td>
<td>Possible corruption</td>
<td>Exit the patient database, make a copy/backup of the problem database, and then compact the original problem database. Enter the database and check to make sure that no data was lost. If data was lost, delete the compacted database, and restore the copy/backup made. Then, create a new database, and merge in the problem database. Now repeat the process for the QC database.</td>
</tr>
<tr>
<td>Get the error “Unrecognized database format”</td>
<td>Possible corruption</td>
<td>Exit the patient database, make a copy/backup of the problem database, and then compact the original problem database. Enter the database and check to make sure that no data was lost. If data was lost, delete the compacted database, and restore the copy/backup made. Then, create a new database, and merge in the problem database. Now repeat the process for the QC database.</td>
</tr>
<tr>
<td>Get a “Disk or Network” error when all network connections are sound, or the database is stored locally.</td>
<td>Possible corruption</td>
<td>Exit the patient database, make a copy/backup of the problem database, and then compact the original problem database. Enter the database and check to make sure that no data was lost. If data was lost, delete the compacted database, and restore the copy/backup made. Then, create a new database, and merge in the problem database. Now repeat the process for the QC database.</td>
</tr>
<tr>
<td>After compacting, the tracings or test results are missing.</td>
<td>Possible corruption</td>
<td>Exit the software, and restore the copy/backup of the database that was copied. Enter the software and create a new database, then merge the problem database into the new database.</td>
</tr>
<tr>
<td>After compacting, all the data is lost from a database.</td>
<td>Possible corruption</td>
<td>Exit the software, and restore the copy/backup of the database that was compacted. Enter the software and create a new database, then merge the problem database into the new database.</td>
</tr>
<tr>
<td>When exiting the Edit Case window, a gray screen appears.</td>
<td>Known system error.</td>
<td>Enter User Profile Setup, then exit. No changes are required in the User Profile.</td>
</tr>
<tr>
<td>Error received during compacting.</td>
<td>Temporary files from previous compacting action still exist.</td>
<td>Delete temporary file (teg compact.teg).</td>
</tr>
</tbody>
</table>
### Database

<table>
<thead>
<tr>
<th>An excluded sample type is staying included.</th>
<th>The database has samples with the sample type that was excluded.</th>
<th>Somehow get rid of the samples with the sample type you want to get rid of, or change the sample types of those samples.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The sample type you were trying to exclude was L1 or L2</td>
<td>You cannot exclude the sample types L1 or L2</td>
<td></td>
</tr>
</tbody>
</table>
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System Requirements for the TEG® Analytical Software (TAS)

This section lists the system requirements that you must meet before installing the TEG-enabled version and the remote version of TAS.

TEG-Enabled System Requirements

To install and use TAS on a TEG-enabled version (for example, in a laboratory), you need the following:

- 1.6 GHz Pentium 4 processor or higher
- 1 GB RAM or higher
- 10 GB hard drive
- SVGA video adapter running 24-bit color settings in Windows
- CD-ROM drive for installation; recommend CD-RW instead for backup and data transfer
- Network adapter, if network access required
- Available COM port (RS232 9-pin serial port)
- Windows-compatible printer, if hard copy is required
- Uninterruptible power supply (UPS)
- Windows 2000 Professional -- SP4 or higher
- Windows XP Professional -- SP2 or higher

Optional Items

The following items are optional:

- Touch screen interface (requires either additional COM port or USB port)
- Bar code scanner for patient ID information (requires either additional COM port or USB port)
- TCP/IP connection required if Laboratory Information System (LIS) interface is anticipated
- Microsoft Excel if VCurve data will be exported
Remote System Requirements

To install and use TAS on a TEG remote version (for example, in OR, ICU/CCU, ER, etc), you need the following:

- 1.6 GHz Pentium 4 processor or higher
- 1 GB RAM or higher
- 10 GB hard drive
- SVGA video adapter running 24-bit color settings in Windows
- CD-ROM drive for installation; recommend CD-RW instead for backup and data transfer
- Network adapter, if network access required
- Windows-compatible printer, if hard copy is required
- Windows 2000 Professional -- SP4 or higher
- Windows XP Professional -- SP2 or higher

Optional Items

The following items are optional:

- Touch screen interface (requires either additional COM port or USB port)
- Microsoft Excel if VCurve data will be exported
Installing the TEG Analytical Software (TAS)

To install TAS, follow these steps:

1. Insert the CD.

   The TEG V4.3 – InstallShield Wizard appears.

2. Click the Next button.

3. Follow the prompts and click the appropriate button.

   Important! Depending on the programs that are already installed on your computer, you may experience the following:
   
   • It may seem like the TEG program is frozen during the installation process, especially since there are no progress bars throughout the process. It is very important to not stop the process unless you choose to click the Cancel button.
   
   • You may be instructed to restart the computer during the installation process up to three times

4. When a message appears indicating that the new version of the TEG software was successfully installed, click the Finish button.
Uninstalling TAS

To uninstall your previous version of the software, follow these steps:

Part of the uninstalling process is to delete the existing TEGV4 directory, which contains the old configuration database. **If you need your old configuration database, import it now** (see Importing a Configuration Database for instructions) or make a copy of the Cfg.set file **before you delete the existing database.**

1. From Windows, click **Start** and then select **Settings**.

2. Select **Control Panel**.

3. Double-click on the **Add or Remove Programs** icon to display the **Add or Remove Programs** screen.

4. Highlight **TEG® 4.x** and click on the **Change/Remove** button.

   A screen appears for you to confirm removing the program.

5. Click the **Yes** button.

   A screen appears while the program is uninstalling followed by a screen indicating that the program was successfully uninstalled.

6. Click the **OK** button.

   You are returned to the **Add or Remove Programs** screen.

7. Close all screens using your preferred method.

8. Open Windows Explorer and go to the **TEG 4** folder (the default is `c:\Program Files\TEGV4`)

   **Important!** The next step is to delete the existing TEGV4 directory, which contains the old configuration database. **If you need your old configuration database, import it now** (see Importing a Configuration Database for instructions) or make a copy of the Cfg.set file.

9. **Delete the TEGV4.x folder.**
Enabling Remote Viewing (for System Administrator)

To enable remote viewing, follow these steps:

**Note:** This feature uses SQL Server Express, which is a Microsoft product, not a Haemoscope product. The management studio is a free utility provided by Microsoft and is included in the installation as a convenience to Haemoscope customers.

Before you begin, you must have System Administrator (sa) privileges.

1. From Windows, click the **Start** button and then select **Programs**.
2. Select **Microsoft SQL Server 2005**.
3. Select **Configuration Tools**.
4. Select **SQL Server Surface Area Configuration**.

The SQL Server 2005 Surface Area Configuration screen appears:
5. Click on **Surface Area Configuration for Services and Connections**.

The **Surface Area Configuration for Services and Connections** – localhost screen appears:

![Surface Area Configuration for Services and Connections](image)

6. Go to the box on the left side of the screen and click on **Remote Connections**.

Remember, these instructions apply only to the Haemoscope instance.

Notice that the right half of the screen changes:

![Remote Connections Screen](image)
7. Make sure that the following are selected:
   - Local and remote connections
   - Using TCP/IP only

8. Click the **Apply** button.

   **Note:** If this is the initial system set up, the following screen may appear:

   ![Connection Settings Change Alert](image)

   Changes to Connection Settings will not take effect until you restart the Database Engine service.

9. Click the **OK** button.

10. Select **SQL Server Browser**.

11. Select **Service Status** and then **Automatic**.

12. Click **OK**.

   The SQL Server 2005 Surface Area Configuration screen appears.

13. Restart the computer.
Back up a database

When you back up a database, you are appending the files. You are not overwriting them. To backup a database, follow these steps:

Note: Before you begin, you must have System Administrator (sa) privileges.

1. From Windows, click the Start button and then select Programs.


3. Select SQL Server Management Studio Express.

   The Connect to Server screen appears:

   ![Connect to Server screen](image)

4. Complete the following fields:

<table>
<thead>
<tr>
<th>Field</th>
<th>Entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Server Name</td>
<td>Make sure that <strong>Haemoscope</strong> appears in the name. If it does not, select it from the drop-down menu.</td>
</tr>
<tr>
<td>Authentication</td>
<td>Make sure that <strong>SQL Server Authentication</strong> is displayed. If it is not, select it from the</td>
</tr>
</tbody>
</table>
Field | Entry
--- | ---
drop-down menu. | 
Login | Make sure that **sa** is displayed. If it is not, select it from the drop-down menu. |
Password | Type in **Haemoscope V4_3**

**Note**: If you have changed the password, you need to enter it in this field.

5. Click the **Connect** button.

A screen similar to the following appears:

![Screen Screenshot](image)

6. Go to the Object Explorer side of the screen and double-click on **Databases** to expand the folder.

7. Highlight the database that you want to back up and right-click your mouse.

**Note**: Remember, patient databases end with **.teg** and quality control databases end with **.qc**

8. Select **Tasks** to display the **Task** menu.

![Task Menu](image)

9. Select **Back Up** to display the **Back Up Database** screen:
10. Go to the Destination section of the screen and select the location that you want to back up the database to.

**Note:** If you do not see the location to back up the database to, do the following:

a. Click the **Add** button
b. From the *Select Backup Destination* screen, click the **Browse** button to display the *Locate Database Files* screen
c. Locate the file that you want to back up to or, if you need to add the file name, type it in the File name field making sure to add a `.bak` extension
d. Click **OK**
e. Click **OK** from the *Select Backup Destination* screen
   The path now appears on the *Back Up Database* screen for you to select.

11. Click the **OK** button.

A screen similar to the following appears:

12. Click the **OK** button.
Scheduling Automatic Backups

To schedule an automatic backup, you need to:

- Create a script command to run the backup
- Create a .bat file to call the file to execute the script
- Create a schedule using the .bat file

Detailed steps follow.

Before you Begin

Before you begin, you must have Administrator privileges. You also must be at the **Back Up Database** screen. To access the **Back Up Database** screen do the following:

1. Click **Start**, **Programs**, and then **Microsoft SQL Server 2005**
2. Select **SQL Server Management Studio Express**
3. Click **Connect** and then click **Next**
4. Expand the Databases folder and then right-click on the desired database
5. Select **Tasks** and then select **Back Up** to display the **Back Up Database** screen

Creating the Scheduling Script

1. From the **Back Up Database** screen, click the **Script** drop-down arrow to display the **Script** menu:

   ![Script Menu](image)

   - **Script Action to New Query Window**: Ctrl+Shift+N
   - **Script Action to File**: Ctrl+Shift+F
   - **Script Action to Clipboard**: Ctrl+Shift+C
   - **Script Action to Job**: Ctrl+Shift+M

2. Select **Script Action to File** to display the **Save As** screen.

3. Go to the File Name field and type in the name of the database you want to backup making sure to add the `.sql` extension.

   For example, **pdBackup.sql**

   **Note**: It is recommended that you use the following format for the file name: **databasenameBackup.sql**.

4. Click **Save**.

5. Exit all screens until you reach your Windows screen.

You are now ready to create a .bat file.
Creating a .bat File

After you have created a `pb.sql` and `qc.sql` script commands, you are ready to create a .bat file. The .bat file calls the utility that will execute the backup script.

1. From Windows, right-click your mouse and select **New**.

2. Select **Text Document**.

   A New Text Document.txt icon similar to the following appears:


4. Type in the following, making sure to replace the information in *italic* with information that is specific to your site:

   ```
   C:\Program Files\Microsoft SQL Server\90\Tools\Binn\OSQL.EXE" –U  sa  –P "Haemoscope V4_3" –S "your computer name\haemoscope“ –i “path to backup script file"
   ```

   **Note:** If you change the system administrator’s password, you need to change it here too.

5. From the **New Text Document.txt** –**Notepad**, select **File** and then **Save As**.

6. Go to the File name field, type in a name for this backup batch file making sure to have a .bat extension.

7. Click **Save**.

8. Close the **Notepad** file.

You are now ready to create a schedule using the .bat file.
Creating a Schedule

After you have created a .bat file for the `pb.sql` and `qc.sql` script commands, you are ready to create a schedule to run the scripts.

1. Click **Start, Programs**, and then **Accessories**.

2. Select **System Tools** and then **Scheduled Tasks** to display the **Scheduled Tasks** screen:

3. Double click on **Add Scheduled Task** to access the **Scheduled Task Wizard**:

4. Click **Next** to display the **Select Program to Schedule** screen.

5. Highlight your `.bat` file and click the **Open** button.

   **Note:** If the file is not listed, click the **Browse** button to locate it.

6. Type a name for the task in the open field and click the radio button that indicates how often to perform this task.

7. Click **Next**.
8. Specify the time and day(s) of the week to complete the backup and click **Next**.

9. Complete the remaining tasks in the wizard.
Loading a Database

You can load an exported file into the current database using the load feature. In other words, you can load a version 4.3 database file in the version 4.3 software.

Before You Begin

Before you begin, make sure that:

• You are in the database that you want to move the data into
• No samples are running in the database you are in (even if they are being run on a different computer)

To load a database, follow these steps:

1. From the TAS Main screen, click File and then Load to display the Select a TEG Data File screen:

2. Select the data file that you want to load:

   Note: If you cannot find the database you want:
   a. Go to the Look in field and select the directory that contains the database file
   b. Select the file

3. Click the Open button.

   A Loading window appears while the loading is in progress.
The TAS Main screen appears after the database is successfully loaded.
Restoring a Database

To restore a database from your local drive, follow these steps:

Before You Begin  Before you begin, you must have:

- Administrator privileges.
- All users who are connected to the database to be restored close their TEG software

1. From Windows, click the Start button and then select Programs, Microsoft SQL Server 2005.

2. Select SQL Server Management Studio Express.

3. Click the Connect button.

A screen similar to the following appears:

4. Go to the Object Explorer side of the screen and double-click on Databases to expand the folder.

5. Highlight the database that you want to restore and right-click your mouse.

6. Select Tasks and then select Restore:
7. Select **Database** to display the *Restore Database* screen:

![Image of the Restore Database screen]

8. Click the radio button for the From Device field and then click the **Browse** button to display the *Specify Backup* screen:

![Image of the Specify Backup screen]

9. Click the **Add** button to display the *Locate Backup File* screen.

10. Select the backup file you want to use for the restore and click the **OK** button.

    You are returned to the *Specify Backup* screen.

11. Click the **OK** button to return to the *Restore Database* screen.

12. Go to the bottom section of the screen and click the Restore box that corresponds to the database to use for the restore.

13. Click the **OK** button.
Importing a Database

You can import previous versions of patient or QC databases to the current database. You can only import patient databases when you are in a patient’s database, and you can only import QC databases when you in a QC database.

Before you begin, make sure that you are in the database that you want to import to.

To import a database, follow these steps:

1. From the TAS Main screen, click **File** to display the drop-down menu:

   ![File Menu](image)

   - Open Database...
   - New Database...
   - Compact Database...
   - Import
   - Export...
   - Load ...

2. Select **Import** to display the menu that lists the databases available to import:

   ![Import Menu](image)

   - V1 Data file...
   - V2 Database...
   - V3 Database...
   - V4 Database

3. Choose the database version that you want to import.

   A screen similar to the following appears:
4. Locate the database that you want to import:
   a. Go to the Look in field and select the directory that contains the database file
   b. Select the database

5. Click the **Open** button.

An *Import* screen similar to the following appears:

![Import Screen]

While importing, the number of imported samples is displayed on the left side of the progress screen.

The TAS Main screen appears when the import is successfully completed.
Exporting a Database

You can export data from the current database only. For example, to export QC data, you must be in the QC database not just connected to it.

About Exporting

You can export a patient or QC database in the following formats:

- TEG data file format
- Tab-delimited

The TEG data file format allows you to export an entire or part of a TEG database, which can then be loaded into a new database. If you are exporting part of a database, you may first set the filter to specify the data or choose the samples in the export wizard.

The Tab-delimited format allows you to export the database into Excel or any database or program that accepts tab-delimited data. You also can choose to include supplementary files in the export.

The Steps

To export a patient or QC database, follow these steps:

1. From the TAS Main screen, click File and then Export to display the Export data wizard (1) screen:

2. Choose one of the following:

<table>
<thead>
<tr>
<th>To export...</th>
<th>Do the following...</th>
</tr>
</thead>
<tbody>
<tr>
<td>All data in a database</td>
<td>a. Click All</td>
</tr>
<tr>
<td></td>
<td>b. Click Next</td>
</tr>
<tr>
<td></td>
<td>c. Continue at the Export data wizard (2) screen section</td>
</tr>
<tr>
<td>Data specified through a</td>
<td>a. Click Subset</td>
</tr>
<tr>
<td>To export...</td>
<td>Do the following...</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| filter                           | b. Click Next  
|                                  | c. Continue at the Export data wizard(2) screen section |
| **Note:** You must set the filter before exporting |                                                                                                                                                                                                                  |
| Particular data                  | a. Click **Subset**  
|                                  | b. Click **Let me pick samples**  
|                                  | c. Click **Next**  
|                                  | d. Continue at the **Select samples** screen |
| One particular tracing           | a. Click **Single Tracing**  
| **Note:** You must select the tracing before exporting |                                                                                                                                                                                                                  |
|                                  | b. Click **Next**  
|                                  | c. Continue at the **Export data wizard(2)** screen section |
Export data wizard(2) screen

If you selected any of the following from the Export data wizard(1) screen

- All
- Subset **without Let me pick samples**
- Single Tracing

The Export data wizard(2) screen appears:

1. Select the format for the type of database to export and click the **Next** button.

   The Save As screen appears:
2. Go to the File name field and type in the database name.

3. Click the **Save** button.

The TAS Main screen appears indicating that the database was exported.

**Select samples screen (Exporting Selected Samples)**

If you selected **Let me pick samples** from the *Export data wizard(1)* screen, the *Select samples* screen appears:

1. Highlight the samples you want and click the **OK** button. The following screen appears:

2. Click **OK**.

3. Select the format for the type of database to export and click the **Next** button.

The *Save As* screen appears:
4. Go to the File name field and type in the database name.

5. Click the **Save** button.

The TAS Main screen appears indicating that the database was exported.
Creating a New Database

When you create a new database, the system automatically places the correct extension on the new database name—.teg for a patient database and .qc for a qc database.

To create a new patient or quality control database, follow these steps:

1. From the TAS Main screen, click **File** and then **New Database** to display the **New** screen:

   ![New Screen](image)

   - Click either **Patient database** or **QC database** to indicate the type of database to create
   - Click the **OK** button

   The **New Database** screen appears:

   ![New Database Screen](image)

2. Do the following:

   - Click either **Patient database** or **QC database** to indicate the type of database to create
   - Click the **OK** button

   The **New Database** screen appears:

3. Go to the Choose Server field and select the server.
4. Complete the Enter the Name of New Database field.

5. Click the Done button.

A Creating window, a Populating window and a New window appear for a few moments followed by the New database screen:

6. Click the appropriate button:

   Yes to make the new database the default
   No to not make the new database the default

You are returned to the TAS Main screen displaying the database you just created.
Logging into the CfgUtil.exe

To log into the Configuration Utility (CfgUtil.exe), follow these steps:

1. Open the CfgUtil.exe.

   **Note:** There is more than one way to open this utility. You may have a short cut icon or you may be opening it from your c: drive. The steps listed below are from the c drive as it is the most common location.

   a. From Windows, double-click on the **My Computer** icon
   b. Double-click on **Local Disk (C:)** to display the contents on the C drive
   c. Double-click on **Program Files** to display its contents
   d. Go to **TEGV4_3** and double-click on it to display its contents
   e. Click on **CfgUtil.exe**

      **Note:** Depending on your Windows Explorer settings, **CfgUtil** may appear instead of CfgUtil.exe.

   The **Login** screen appears:

2. Type in the site administrator’s password and click the **Login** button.

   The **System Setup** screen appears:

   You are now logged into CfgUtil.exe.
Importing a Configuration Database

To import a configuration database means to bring an older version of a database file into the current version of software.

Importing a configuration database will **replace the current configuration settings**. Make sure this is what you want to do.

To import a configuration database, follow these steps:

1. Open the CfgUtil.exe.
   - **Note:** There is more than one way to open this utility. You may have a short cut icon or you may be opening it from your c: drive. The steps listed below are from the c drive as it is the most common location.
   a. From Windows, double-click on the **My Computer** icon
   b. Double-click on **Local Disk (C:)** to display the contents on the C drive
   c. Double-click on **Program Files** to display its contents
   d. Go to **TEGV4_3** and double-click on it to display its contents
   e. Click on **CfgUtil.exe**
      - **Note:** Depending on your Windows Explorer settings, **CfgUtil** may appear instead of CfgUtil.exe.

   The **Login** screen appears:

   ![Login Screen](image)

   2. Type in the site administrator’s password and click the **Login** button.
   
   The **System Setup** screen appears:
3. Go to the tool bar and click on **File** to display the **File** drop-down menu:

![System Setup](image)

4. Select **Import .set file** to display **Import .set file** window:

![Import .set file](image)

5. Click the **Yes** button to save the current configuration.

The Export to TEG Data File window appears.

6. Choose a location and name for the file, which will be the backup for your current configuration database.

7. Click the **Save** button.

A window appears for you to confirm that you want to continue and reminds you that that doing so will replace your current configuration database.

8. Click **Yes** to continue.

9. Locate the TEG database that you want to import.
   
   a. Go to the Look in field and select the directory that contains the database file (the default is `c:\Program Files`)
   
   b. Select the TEG V3 or TEG V4.x folder
   
   c. Select the .set file to import

10. Click the **Open** button.

    The **System Setup** window appears.

11. Click the **Done** button to exit the CfgUtil.exe.
Exporting a Configuration Database

To export a configuration database, follow these steps:

1. Open the CfgUtil.exe.

   **Note:** There is more than one way to open this utility. You may have a short cut icon or you may be opening it from your c: drive. The steps listed below are from the c drive as it is the most common location.

   a. From Windows, double-click on the **My Computer** icon
   b. Double-click on **Local Disk (C:)** to display the contents on the C drive
   c. Double-click on **Program Files** to display its contents
   d. Go to **TEGV4_3** and double-click on it to display its contents
   e. Click on **CfgUtil.exe**

   **Note:** Depending on your Windows Explorer settings, **CfgUtil** may appear instead of **CfgUtil.exe**.

   The **Login** screen appears.

2. Type in the site administrator’s password and click the **Login** button.

   The **System Setup** screen appears:
3. Go to the tool bar and click on **File** to display the *File* drop-down menu:

![System Setup](image)

4. Select **Export** to display *Export to TEG®Data File* window.

5. Choose a location and file name.

6. Click the **Save** button.

   An *Exporting* window appears followed by the *System Setup* window.

7. Click the **Done** button to exit the CfgUtil.exe.
Managing Profiles

The *manage profiles* feature allows you to do the following:

- Add a profile
- Delete a profile
- Set a default profile
- Change the password for the Site Administrator (SA)

Accessing Manage Profiles

To access the *manage profiles* feature, follow these steps:

1. Open the CfgUtil.exe.

   **Note:** There is more than one way to open this utility. You may have a short cut icon or you may be opening it from your c: drive. The steps listed below are from the c drive as it is the most common location.
   a. From Windows, double-click on the *My Computer* icon
   b. Double-click on *Local Disk (C:)* to display the contents on the C drive
   c. Double-click on *Program Files* to display its contents
   d. Go to *TEGV4_3* and double-click on it to display its contents
   e. Click on *CfgUtil.exe*

      **Note:** Depending on your Windows Explorer settings, *CfgUtil* may appear instead of CfgUtil.exe.

      The *Login* screen appears.

      ![Login Screen]

2. Type in the site administrator's password and click the *Login* button.

   The *System Setup* screen appears:
3. Do the following:

- Make sure that Site Administrator is displayed in the field next to the **Manage profiles**... button and select it if it is not
- Click on the **Manage profiles**... button to display the **Security Identification** screen:

![Security Identification](image)

4. Do one of the following:

<table>
<thead>
<tr>
<th>If you want to...</th>
<th>Continue at...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add a user profile</td>
<td>Adding a Settings Profile</td>
</tr>
<tr>
<td>Delete a user profile</td>
<td>Deleting a Profile</td>
</tr>
<tr>
<td>Set a default profile</td>
<td>Setting a Default Profile</td>
</tr>
<tr>
<td>Change the password for the SA</td>
<td>Changing the Password for the SA Settings Profile</td>
</tr>
</tbody>
</table>
Addendum

Adding a Settings Profile

The *add profile* feature allows you to add a profile to the TEG system. This profile contains the preferences for viewing data on the TEG system.

To add a user settings profile, follow these steps:

**Before You Begin**

Before you begin, you must have:

- Logged into the CfgUtil.exe to display the *System Setup* screen
- Clicked on the *Manage profiles...* button

1. From the *Security Identification* screen, click the *Add profile* button.

The *Security definition* screen appears:

2. Go to the Profile name field and type in the user name.

3. Click the *OK* button.

The *Security Identification* screen appears. Notice that the profile you added appears in the Profiles section of the screen.
4. Click the **Done** button.

You are returned to the *System Setup* screen.

5. Click the **Done** button again to exit the Config utility.
Deleting a Profile

The *delete profile* feature allows you to delete a profile from the TEG system.

To delete the settings for a profile, follow these steps:

**Before You Begin**

Before you begin, you must have:

- Logged into the CfgUtil.exe to display the *System Setup* screen
- Clicked on the *Manage profiles...* button

1. From the *Security Identification* screen, highlight the profile that you want to delete.
2. Click the *Delete profile* button.

   A screen appears for you to confirm the delete.

   ![Delete profile dialog](image)

   **Delete profile**
   
   *Are you sure you want to delete this profile?*

   ![Yes/No buttons](image)

3. Click the *Yes* button to confirm the delete.

   The *Security Identification* screen appears. Notice that the profile you deleted no longer appears in the Profiles section of the screen.

4. Click the *Done* button.

   You are returned to the *System Setup* screen.

5. Click the *Done* button again to exit the Config utility.
Changing the Password for the Site Administrator (SA) Settings Profile

The change password feature allows you to change the password for the site administrator on the TEG system.

To change the password for the SA, follow these steps:

Before You Begin
Before you begin, you must have:

- Logged into the CfgUtil.exe to display the System Setup screen
- Clicked on the Manage profiles… button

1. From the Security Identification screen, highlight Site Administrator.

2. Click the Change password button.

The Security definition screen appears:

3. Go to the Profile Password field and type in the new password.

   Important! The SA password must be at least three characters long.

   For security reason, an asterisk appears for each character that you type in.

4. Go to the Confirm Password field and retype the password that you just entered. Again, an asterisk appears for each character that you type in.

5. Click the OK button.

   Note: If the passwords in the two fields do not match, a message appears asking you to reenter the passwords.

   You are returned to the Security Identification screen.
Setting a Default Profile

You can set a particular, non-administrator profile as a default. When the user logs in, this will be the default profile for the user to select. The user may still change the profile in the log in screen.

To set a default profile, follow these steps:

Before You Begin

Before you begin, you must have:

- Logged into the CfgUtil.exe to display the System Setup screen
- Clicked on the Manage profiles… button

1. From the Security Identification screen, highlight the profile.

2. Click the Set as default button.
   
   Notice that the Set as default button becomes shaded out.

3. Click the Done button.
   
   You are returned to the System Setup screen.

4. Click the Done button again to exit the Config utility.
Setting a Filter for Patient Selection (Config Utility)

You can set a feature so that after the user logs into the system, a patient list automatically appears for the user to select the patients to view.

To set the select patient screen feature, follow these steps:

1. Open the CfgUtil.exe.
   
   **Note:** There is more than one way to open this utility. You may have a short cut icon or you may be opening it from your c: drive. The steps listed below are from the c drive as it is the most common location.
   
   a. From Windows, double-click on the **My Computer** icon
   b. Double-click on **Local Disk (C:)** to display the contents on the C drive
   c. Double-click on **Program Files** to display its contents
   d. Go to **TEGV4_3** and double-click on it to display its contents
   e. Click on **CfgUtil.exe**
      
      **Note:** Depending on your Windows Explorer settings, **CfgUtil** may appear instead of CfgUtil.exe.

   The **Login** screen appears.

   ![Login Screen]

   2. Type in the site administrator’s password and click the **Login** button.

   The **System Setup** screen appears:
3. Click on the **System** tab to display the System wide section:

4. Click on the **Show select patient screen** entry so that a check mark (✓) appears in the corresponding check box.

5. Click the **Done** button.
Viewing All Patients (Config Utility)

You can set a feature that allows the user to view all patient samples when the patient filter is not set.

To do this, follow these steps:

1. Open the CfgUtil.exe.
   
   **Note:** There is more than one way to open this utility. You may have a short cut icon or you may be opening it from your c: drive. The steps listed below are from the c drive as it is the most common location.
   a. From Windows, double-click on the My Computer icon
   b. Double-click on Local Disk (C:) to display the contents on the C drive
   c. Double-click on Program Files to display its contents
   d. Go to TEGV4_3 and double-click on it to display its contents
   e. Click on CfgUtil.exe
      
      **Note:** Depending on your Windows Explorer settings, CfgUtil may appear instead of CfgUtil.exe.

   The Login screen appears:

   ![Login Screen](image)

2. Type in the site administrator's password and click the Login button.

   The System Setup screen appears:

   ![System Setup Screen](image)

3. Click on the System tab to display the System wide section:
4. Click on the **Show samples on cancel of select patient screen** entry so that a check mark (✓) appears in the corresponding check box.

Remember, this feature allows the user to view all patient samples when the patient filter is not set.

5. Click the **Done** button.
Logging Into the TEG Analyzer Software (TAS)

When you access the TAS login screen, a default profile is automatically included. This profile will determine the program settings.

To log into TAS, follow these steps:

1. Double-click your left mouse button on to start the program.
   A screen displays for a few moments showing the program title and copyright information followed by the Login screen

   ![Login Screen](image)

   The information and diagnostic statements in the TEG® software are based on information contained in standard medical publications and reference materials. Users are solely responsible for the selection, use, and suitability of interpretation or treatment recommendation in general or in any particular instance. Clinicians should use their own medical judgment, together with assessment of the patient's clinical condition, when considering TEG® results and making diagnosis and treatment decisions.

2. Go to the User name field and select your name from the pull-down list.
   
   **Note:** If you have a TEG-enabled version of the software, a QC database text box automatically appears in the Databases section of the screen.

3. If you were assigned a password, go to the Password field and type it in exactly as it is defined on the system. Remember, passwords are case sensitive, upper and lower case letters must match exactly.
For security reasons, your password does not display. An asterisk (*) appears for each character you type.

4. Go to the Databases section of the screen and check that the correct patient database is displayed.

   **Note:** If you do not see the desired database, do the following:
   a. Click the **Locate** button
   b. Complete the **Locate** Database screen
   c. Click the **Done** button

   You are returned to the **Login** screen, which displays the desired database.

5. Click the **OK** button.

   **Note:** If you set a filter for patient selection, the **Patient screen** appears. Make your selection and click **Done**.

The central program screen appears. This screen is referred to as the **TAS Main** screen.
Adding the Date and Time for Specimen Collection

To include the date and time that the blood was drawn, follow these steps:

1. From the TAS Main screen, click on the patient that you want to include the time and date that blood was drawn.

2. Click to display the Detail screen:

3. Click the Sample tab to display the Sample screen:

4. Go to the Date Drawn field and type in the date the blood was drawn.

5. Go to the Time Drawn field and type in the time the blood was drawn.

6. Click to return to the TAS Main screen.
Adding the RapidTEG TEG ACT Parameter

To include the RapidTEG TEG ACT parameter, follow these steps:

1. From the TAS Main screen toolbar, select **Options**.

2. Select **User Profile Setup** to display the **User profile setup** screen.

3. Click on the **SampleTypes** tab.

4. Click the **Include** button to display the **Include Sample type** screen.

5. Go to the Include column and click on the box that corresponds to TEG ACT so that a checkmark appears in the box.

6. Click the **Done** button.
7. From the User profile setup screen, highlight TEG ACT and click the Done button.

You are returned to the TAS Main Screen.