TEG® 5000 Thrombelastograph® Hemostasis System

A drop of blood… the whole picture

- *First to reflect cell-based model of hemostasis*
- *Thrombus generation through first derivative velocity curve*
- *Measures prothrombotic state as well as hemorrhagic*
- *PlateletMapping™ for personalized antiplatelet therapy*

haemoscope™

TEG® 5000 Thrombelastograph® Hemostasis System

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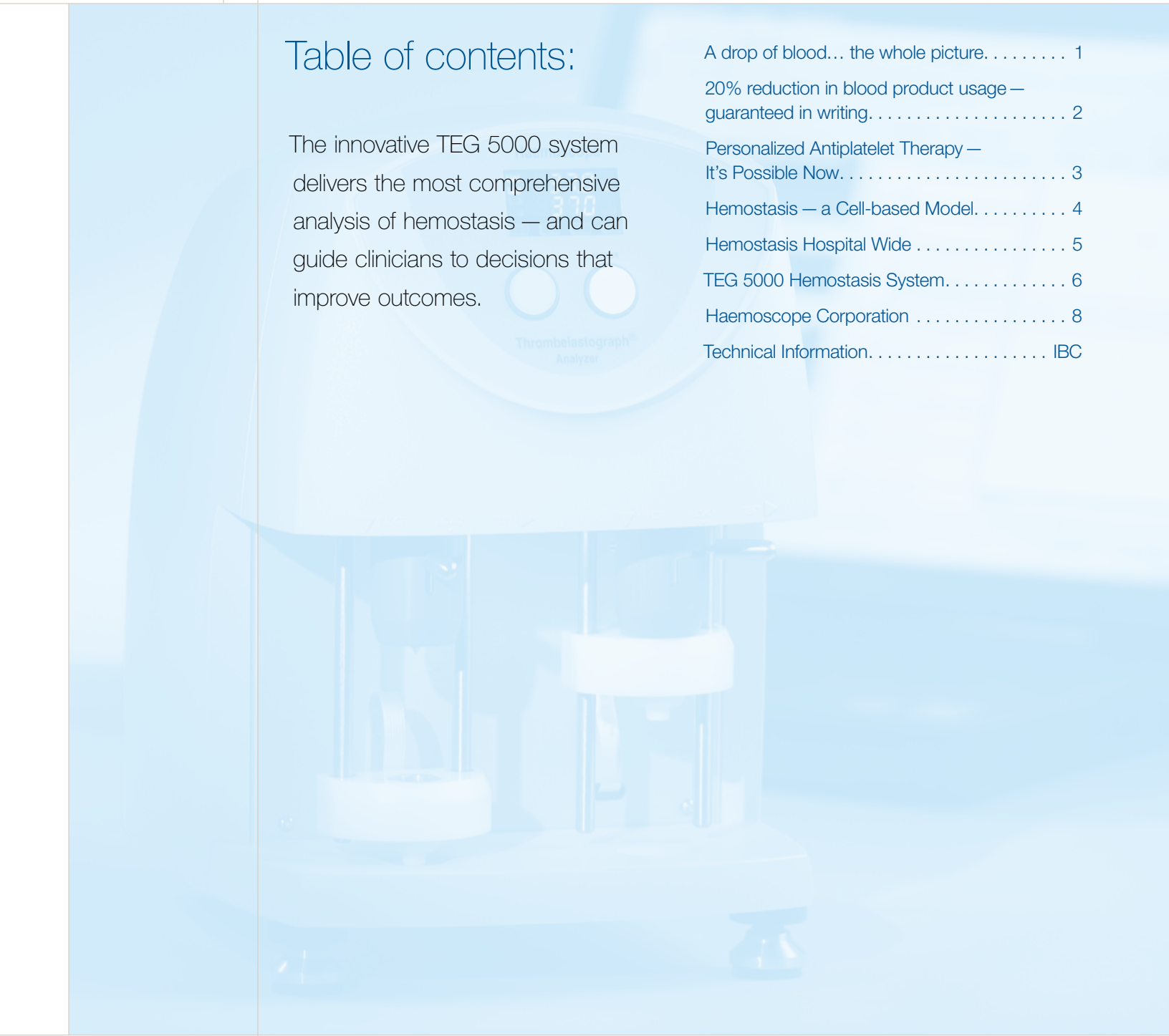
The innovative TEG 5000 system delivers the most comprehensive analysis of hemostasis — and can guide clinicians to decisions that improve outcomes.



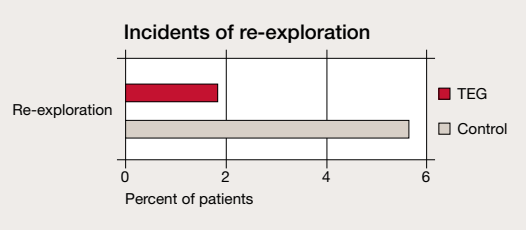
A drop of blood... the whole picture

A comprehensive analysis of hemostasis from a single whole blood sample

How do you assess your patient's hemostasis state? Do you rely on aPTT, PT, TT, INR, FDP, and similar tests?

- These are *plasma* tests, so how do you measure the effect of cellular elements?
- These are *isolated* tests, so how do you integrate potentially contradictory results?
- These have *static end points* (e.g., fibrin formation) – when only 5% of thrombin has been generated, so how do you assess the effect of reactions that take place later in the process?
- These tests measure *bleeding,* so how to you measure a prothrombotic state?

Monitoring hemostasis using the cell-based model requires a whole blood test to measure the net effect of the interactions among platelets, coagulation factors, and other cellular elements. The TEG 5000 Hemostasis System, with a drop of whole blood, draws a picture of the delicate hemostasis balance or imbalance present—depicting all phases of hemostasis from initial fibrin formation through clot lysis. It quantifies hemorrhagic, thrombotic, and fibrinolytic states so you can stratify risk of bleeding and ischemic events and personalize therapies.



What exactly does the TEG 5000 Hemostasis System provide?

- A single instrument that provides a total view of your patient's hemostasis: measurements of clotting time, clot formation kinetics, clot strength, and clot lysis from a single 360 µl whole blood sample—including assessment of the effects of antiplatelet drugs
- A single system that can be used both point of care as well as in a centralized clinical laboratory
- Real-time hemostasis data that can be viewed anywhere in the hospital, or even outside the hospital
- The only system that reflects the cell-based hemostasis model.

What does this mean for your institution?

Availability of individual parameters as well as the net result of all the interactions of all the components of patient whole blood hemostasis, resulting in:

- Ability to stratify risk of bleeding and ischemic events
- Reduced use of blood products and pharmaceuticals and their attendant complications
- Reduced re-exploration
- Reduced costs
- Improved clinical outcomes.

This results in better patient care—accurate diagnosis, optimal therapy, and improved clinical outcomes... Can you afford to make hemostasis decisions without it?

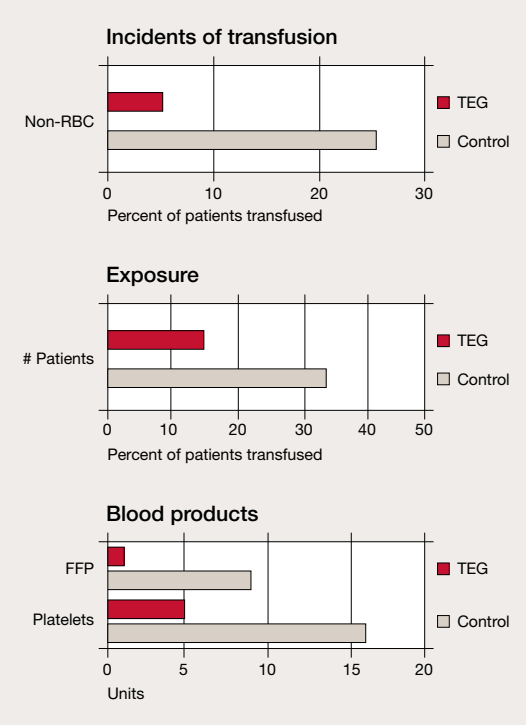
20% reduction in blood product usage — guaranteed in writing

Better, more informed decisions about blood product administration

Blood transfusions can be lifesaving when administered properly — proper product, proper dose, and proper time.

They can also be deadly.

A recent study by Rao et al[1] of over 24,000 ACS patients from the GUSTOIIb, PURSUIT, and PARAGON8 trials shows that a blood transfusion can double the risk of death and triple the risk for another heart attack within a month. Spiess et al[2] associated platelet transfusion during CABG with increased risk for serious adverse effects, showing a threefold increase in stroke tendency and fivefold increase in death tendency.



A related problem with blood transfusions is the availability of blood product itself. Each holiday period, appeals to donors are issued to avert critical blood shortages. Many blood bank centers are able to provide only one or two days worth of blood supplies during peak usage periods. As diseases such as hepatitis and HIV continue to spread, blood sources continue to dwindle.

These issues, along with others related to blood product usage such as complications and length of hospital stay due to exposure to unneeded transfusions, can be mitigated through better, more informed decisions about blood product administration.

Royston and von Kier[3], and Shore-Lesserson[4], among others, have all shown that when TEG hemostasis monitoring was used, they were able to reduce blood product usage, morbidity and mortality, and length of hospital stay.

Can you name another manufacturer of a hemostasis system that will provide a guarantee — in writing — that your institution will reduce blood product usage by 20%, or it will refund your money? We guarantee ours.

[1] Rao SV, Jollis JG, Harrington RA, Granger CB, Newby LK, Armstrong PW, Moliterno DJ, Lindblad L, Pieper K, Topol EJ, Stamler JS, Califf RM. Relationship of blood transfusion and clinical outcomes in patients with acute coronary syndromes. JAMA. 2004 Oct 6; 292(13): 1555–62.

[2] Spiess BD, Royston D, Levy JH, Fitch J, Dietrich W, Body S, Murkin J, Nadel A. Platelet transfusions during coronary artery bypass graft surgery are associated with serious adverse outcomes. Transfusion. 2004 Aug; 44(8): 1143–8.

[3] Royston D, von-Kier S "Reduced haemostatic factor transfusion using heparinase-modified thrombelastography during cardiopulmonary bypass." British Journal of Anaesthesia. 2001; 86: 575–578.

[4] Shore-Lesserson L, Manspeizer HE, DePerio M, et al. Thromboelastography-guided transfusion algorithm reduces transfusions in complex cardiac surgery. Anesth Analg 1999; 88: 312–9.

Personalized Antiplatelet Therapy—It's Possible Now

Individualize all hemostasis therapies, not just antiplatelet therapy

Everyone agrees that personalized antiplatelet therapy is desirable and looks forward to the future when personalized antiplatelet therapy is possible. But the future is *now,* and personalized antiplatelet therapy is possible *today.* What you need are two end point measurements:

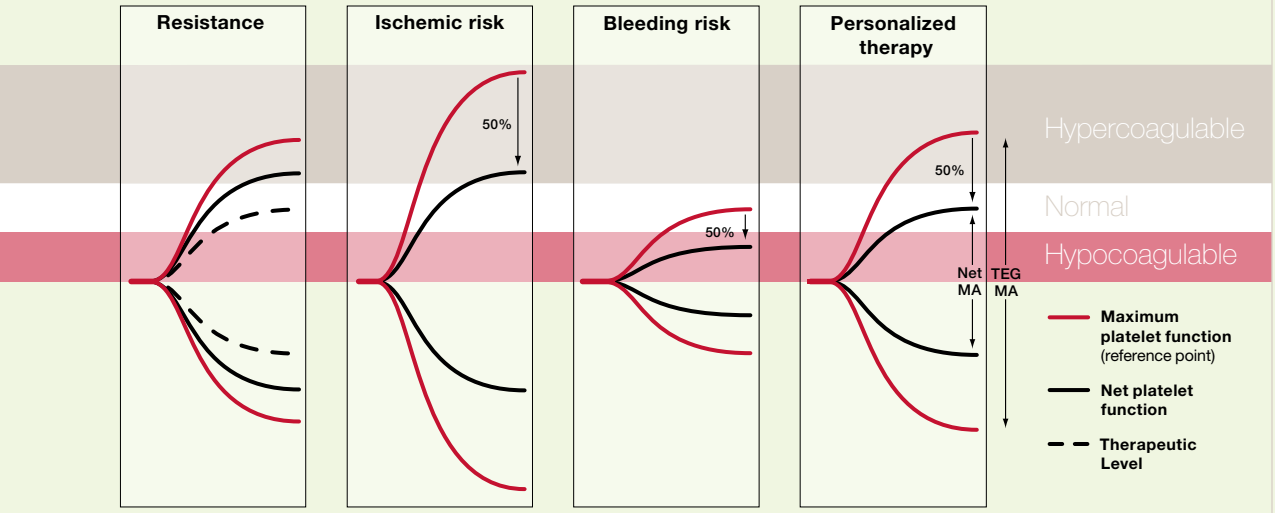
- A patient's maximum platelet function
- Platelet inhibition relative to their own maximal platelet function.

Haemoscope's TEG 5000 system with our new PlateletMapping™ assays provide this information...today.

- TEG analysis provides the measure of maximum platelet function, so you know the degree of hypercoagulability and extent of inhibition needed.
- The PlateletMapping assay reports the percent inhibition and net platelet function.
- So you know:
  - Whether patients are resistant to antiplatelet therapy
  - The effect of the therapy
  - Whether they are at their therapeutic level
  - Their risk for ischemic or bleeding event.

Patients may be at risk for an ischemic event when they are prothrombotic and antiplatelet drugs are suspended before surgery, or at risk for a bleeding event post-op when they are not prothrombotic and are on antiplatelet agents.

The rationale for using two end points is illustrated in this graphic, which shows the effect of 50% inhibition on different patients:



This patient begins as prothrombotic, and continues so despite therapy. He is not inhibited to the therapeutic level and is still exposed to the risk of an ischemic event.

This patient's reference point is extremely prothrombotic and he remains prothrombotic and at risk of an ischemic event, even at 50% reduction in platelet function.

This patient starts with normal platelet function, and reducing it by 50% makes him hypocoagulable with increased risk of hemorrhage.

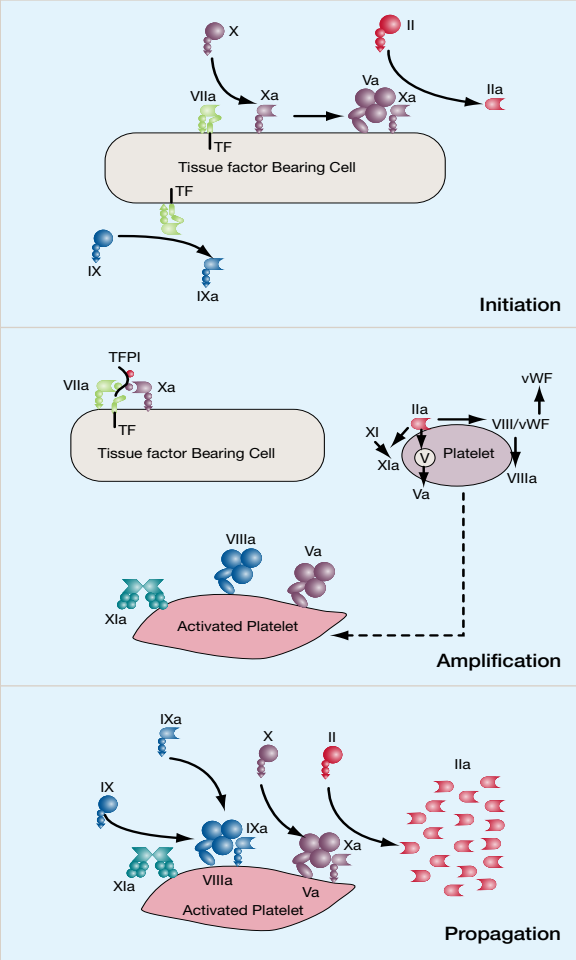
This patient begins as moderately prothrombotic, and a 50% reduction takes him to normal platelet function, reducing the probability of an ischemic event.

Hemostasis — a Cell-based Model

Recognizing the role of the platelet and specific cellular receptors

"Normal hemostasis is controlled activation of clot formation and lysis to prevent hemorrhage without [inappropriate] thrombosis" according to Laposata.[5]

Hemostasis is a balancing act—and when the system is in balance, when the myriad components of hemostasis are interacting at appropriate levels and in appropriate ways, there is neither bleeding nor inappropriate clotting. When the hemostatic system is out of balance, the result can be disastrous hemorrhage or thrombosis.



The traditional way of viewing hemostasis has been as separate intrinsic and extrinsic coagulation systems, with a sequential waterfall effect of coagulation mechanisms and control mechanisms of feedback amplification and inhibition.

- These views were based on a plasma milieu, and are not applicable in vivo in moving blood.
- Routine tests such as PT and aPTT are based on this model and measure coagulation factor interaction in plasma, without the participation of platelets.

These outdated views are being augmented with a better understanding of cell-based hemostasis that recognizes the role of the platelet and specific cellular receptors for coagulation proteins. Hoffman and Monroe[6] have proposed that the cell-based model occurs in three overlapping stages:

- Initiation: occurs on a tissue factor bearing cell
- Amplification: platelets and cofactors are activated
- Propagation: large amounts of thrombin are generated on the platelet surface.

The TEG 5000 system reflects the cell-based model of hemostasis, using a whole blood sample to measure:

- The *net effect* of the interaction of all hemostatic components, plasmatic and cellular elements—especially platelets.
- *All phases* of hemostasis from clot initiation through propagation through lysis.

[5] Laposata M et al. *The Clinical Hemostasis Handbook.* Year Book Medical Publishers, 1989.

[6] Hoffman M, Monroe DM. A cell-based model of hemostasis. Thromb Haemost. 2001 Jun; 85(6): 958–65.

Hemostasis Hospital Wide

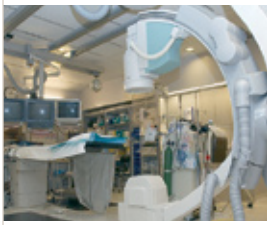
Maximum efficiency and availability throughout the hospital

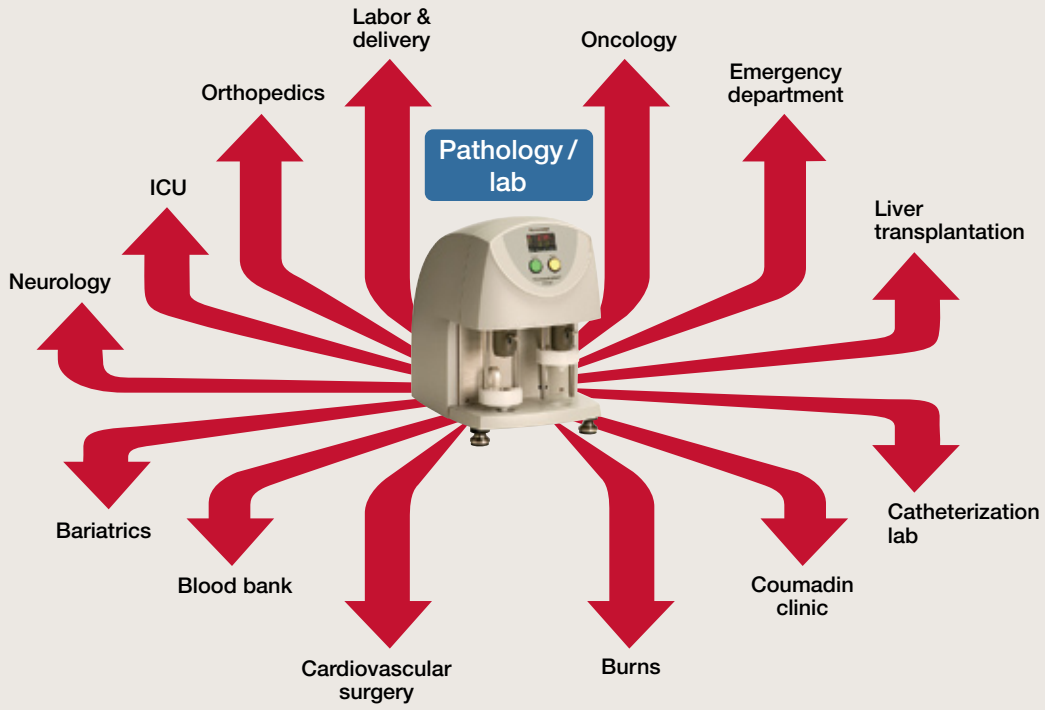
Issues in bleeding and thrombosis are shared across nearly all hospital specialty areas, from bariatrics to orthopedics. Consistent use of TEG-guided hemostasis and blood management protocols can reduce risks associated with both bleeding and thrombosis... reducing both blood product usage and all the undesirable and life-threatening complications associated with blood product transfusions. Identifying a prothrombotic state and treating appropriately can reduce the risks and consequences of ischemic events. TEG analysis can help risk stratify a patient's prothrombotic state and guide and monitor therapy, including personalizing use of various therapies, including anticoagulants and antiplatelet drugs.

The TEG 5000 Hemostasis System is suited for both central laboratory and point of care use.

Point-of-care use provides immediate results at the patient's bedside, as might be appropriate in critical surgical situations such as cardiovascular or liver surgery.

Whole blood samples can be sent for analysis in the central laboratory and results reported in real time via remote workstations located anywhere on the hospital network. Under the leadership of a pathologist/hematologist, the laboratory setting provides a centralized point for sample analysis and interpretation. This maximizes efficiency and availability of hemostasis information throughout the hospital.





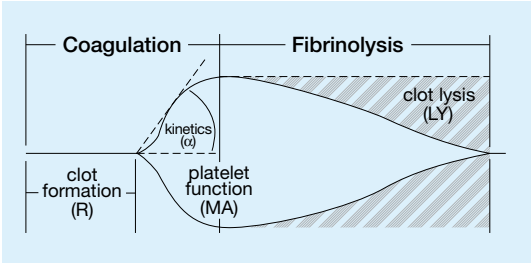
The TEG® 5000 Hemostasis System

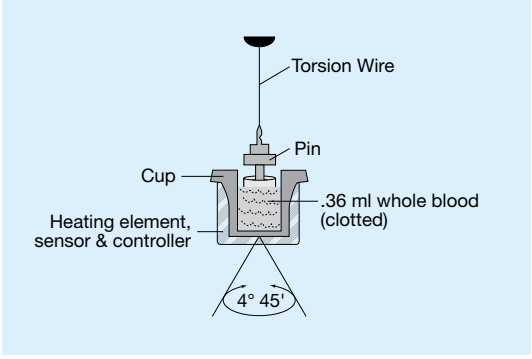
A drop of blood… the whole picture

TEG 5000 technology

The TEG analyzer, using a small whole blood sample, produces results that document the interaction of platelets with the protein coagulation cascade from the time of placing the blood in the analyzer until initial fibrin formation (R), clot formation rate and strengthening (α), and fibrin-platelet bonding via GPIIb/IIIa (MA), through eventual clot lysis (LY).

TEG software displays both qualitatively and quantitatively the two distinct parts of hemostasis — the part that produces the clot and the part that causes the breakdown of the clot. It shows the balance or degree of imbalance in the patient's hemostasis system, highlights any areas of deficiency or excess, and offers a precise view of the patient's hemostasis condition.





If the hemostasis system is not in balance, the TEG results show where the imbalance lies. Is the enzymatic reaction too fast or too slow, as shown by the R parameter? Is there too much functional fibrinogen, or is the fibrinogen level too low, as depicted by the alpha parameter? Is there too much or too little platelet function, as represented by the MA parameter? The TEG system, because of its unique ability to measure all phases of hemostasis, is able to produce a profile that shows the net effect of all the interactive, dynamic processes involved in hemostasis, and, as such, can be used effectively for diagnostic, therapeutic, and risk assessment purposes.

The TEG system measures the clot's physical properties by the use of a cylindrical cup that holds the blood as it oscillates through an angle of approximately 5 degrees The 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 and fibrin-platelet bonding have linked the cup and pin together. The strength and rate of these bonds affect the magnitude of the pin motion such that strong clots move the pin directly in phase with cup motion. As the clot retracts, these bonds are broken and transfer of cup motion is diminished. A mechanical-electrical transducer converts the rotation of the pin into an electrical signal that can be monitored by a computer.

TEG analytical software

The TEG 5000 hemostasis system includes the TEG analytical software. This innovative software delivers the data you need for effective hemostasis management—along with the quality assurance features and flexibility that establish the TEG 5000 hemostasis system as a powerful tool you can rely on for better patient care.

The software helps you accurately and easily assess risk of both hemorrhage and thrombosis and improve clinical outcomes.

- Extensive test panel, including antiplatelet therapy results
- Overlaid patient waveforms for comparison, including normal waveform
- Software assistance for interpreting results
- Free text notes for samples and cases
- Highlighting of clinical trigger values

Connectivity

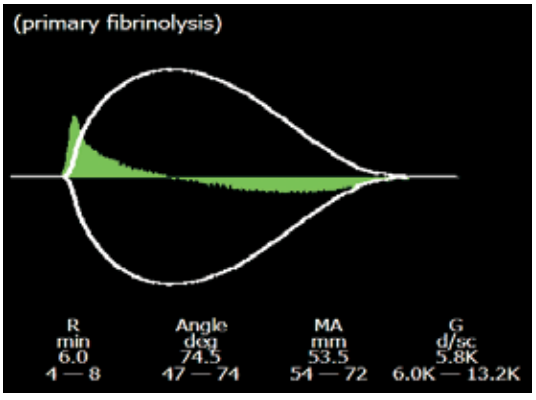
- Real-time remote viewing throughout the hospital
- Offline reports via e-mail to PCs, PDAs* and cell phones* through eConsult
- HIS/LIS interface capable through HL7

Reporting capabilities

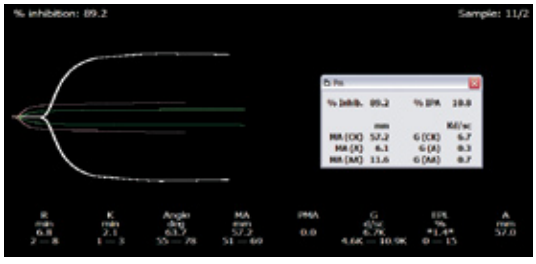
- Single and multiple sample report for paper output
- Case summary for trend analysis

Quality assurance

- Levy-Jennings trend reporting for normal and abnormal controls
- Password protected access
- Reminders to run control samples and alerts when control samples are out of range
- Capture and reporting of corrective actions
- Calibration and electronics testing with full reporting capability



The first derivative (green shape) shows thrombus formation information as well as lysis information superimposed on the usual TEG waveform.



PlateletMapping results indicating inhibition of 89% and inhibited platelet aggregation of 10.8%. In addition, the typical TEG parameters are listed at the bottom of the screen for the white sample.

** Devices must be capable of e-mail with graphical attachments*

Haemoscope Corporation

Commited to improving patient care

Haemoscope Corporation is the home of the classic TEG® 5000 (Thrombelastograph®) Hemostasis System. Haemoscope develops and supports the current state-of-the-art TEG 5000 analyzer, which is based on the original, proven rotating-cup technology that provides maximum sensitivity and software-optimized vibration damping. We are committed to continuous enhancement of the instrument, the analytical software, and the reagents and assays used in hemostasis testing. We are also committed to world-class training and technical support.

Haemoscope owns the trademarks TEG and Thrombelastograph, and thousands of worldwide peer-reviewed publications attest to the usefulness of thrombelastography in the management of hemostasis in obstetrics, trauma, neurosurgery, DVT, the monitoring and differentiation among platelet antagonists, and monitoring of artificial surface devices including heart assist devices and total artificial hearts.

Haemoscope is committed to improving patient care in all aspects of hemostasis as expressed in our mission statement:

Haemoscope's mission is to improve patient care by designing, manufacturing, distributing and supporting the best tools possible to measure all phases of hemostasis. Haemoscope Corporation strives to stay on the leading edge of medicine and technology and to continuously improve the management of hemostasis.

Integrity, dedication and innovation are the core values that drive our company and are critical factors in our success.

To these ends and applying these values, Haemoscope has adopted the slogan "Home of the TEG® system" to show its stewardship of the premier technology and gold standard in the measurement of hemostasis.

Technical information

Specifications

2 independent measuring channels per analyzer, up to 8 channels per computer connection through A/D box

A/D box, cables, and software

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

Power – power supply in protection class II, transformer with thermal cutoff and monitored safety insulation resistant to tropical conditions.

220V model: operating voltage 230V, 50 Hz, rated current 0.21 A, max power take-up 46W

120V model: operating voltage 120V, 60 HZ, rated current 0.42 A, max power take-up 46W

Initial warm-up time – less than 5 minutes to warm sample cups/pins

Operating position – level adjusted by leveling feet and level

Environment – vibration free position, +15 to +30°C, no solar radiation and storage temperature -30 to 50°C.

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

Weight – 5.4kg (12 lb)

Requirements

Computer required for TEG® system operation, to be obtained from your IT or purchasing departments, or through another external source, configured as follows:

Computer configurations

A) TEG-enabled version (e.g., Laboratory)

1 GHz Pentium III processor or higher

512 MB RAM

10 GB hard drive

SVGA video adapter running 24-bit color setting 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 (serial RS232)

Windows-compatible printer, either color or black & white, if hard copy required

Uninterruptable power supply (UPS) for computer and/or TEG® analyzer

Optional: Touch screen interface (requires either additional COM port or USB port)

Bar code scanner for patient ID and operator ID information (requires additional COM port)

B) Remote version (e.g., OR, ICU/CCU, ER, etc.)

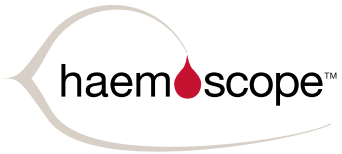
As above for TEG-enabled, except no COM port required

Optional: Touch screen interface (requires either available COM port or USB port)

Operating System

Windows 2000 or 2000 Professional

Windows XP



Haemoscope Corporation
6231 West Howard Street
Niles, Illinois 60714-3403 USA
www.haemoscope.com

800 GET A TEG (438 2 834)
847.588.0453 phone
847.588.0455 fax
info@haemoscope.com

home of the TEG® hemostasis system

Partial list of other product information available from your local representative

- PlateletMapping™ brochure
- Version 4 Software brochure and version 4.2 update sheet
- Personalized Antiplatelet Therapy, Focus On: Cardiac Catheterization report
- TEG 5000 Hemostasis System in Cardiac Catheterization brochure

Training materials

TEG 5000 Operator

- Basic Operator Training Video
- Operator Trainer Guide
- Operator Training Workbook

Clinical

- Basic Clinical Training CD
- Basic Clinical Training Workbook

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