Product Data Sheet

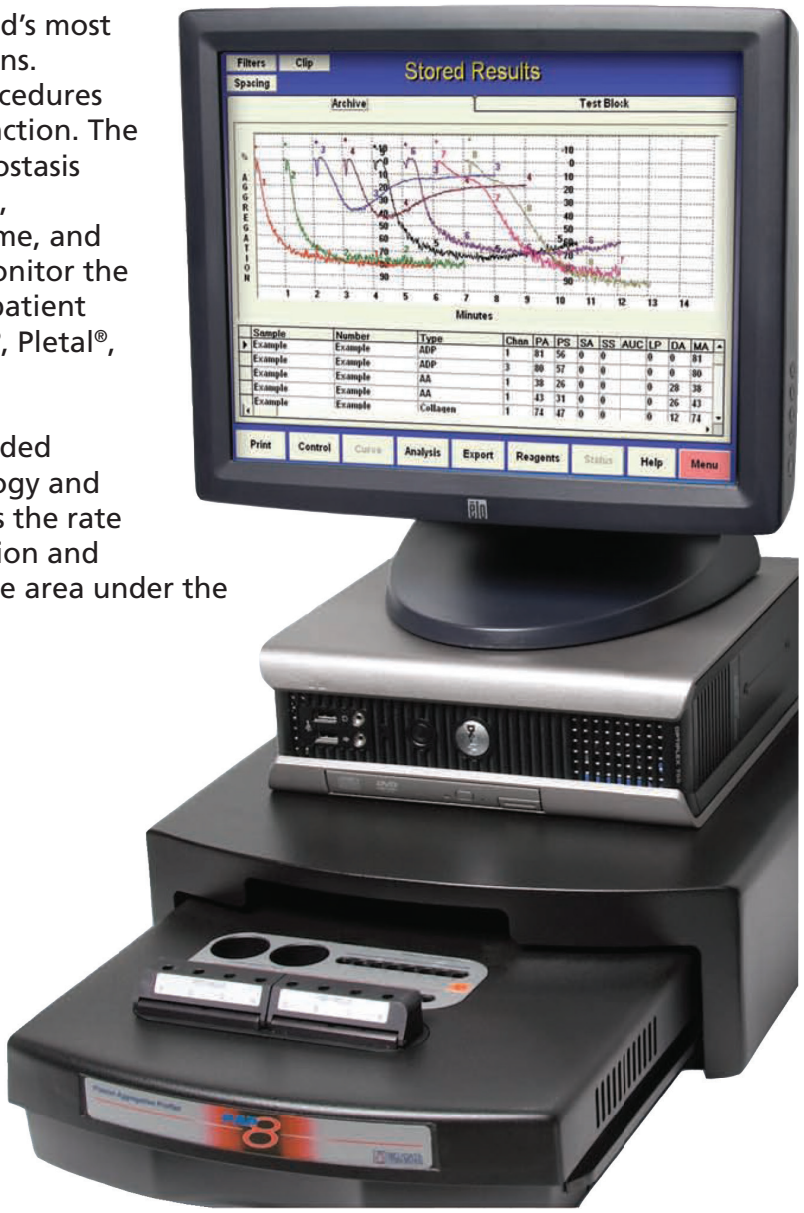
PAP-8E Platelet Aggregation Profiler

The Gold Standard for reliable Results and Ease-of-use.

- Ristocetin CoFactor Activity
- Routine Aggregation Testing
- Anti-Platelet Drug Assessment

Trusted Accuracy, Best-in-Class Performance, Simple & Fast Operation

The PAP-8E from Bio/Data Corporation is the world's most advanced aggregometer for laboratory applications. Exceptional ease-of-use and standardised test procedures allow for rapid and routine testing of platelet function. The PAP-8E is designed to support diagnoses of haemostasis disorders including von Willebrand Disease (vWD), Glanzmann's disease, HIT, Bernard Soulier Syndrome, and Sticky Platelet Syndrome as well as to precisely monitor the use of anti-platelet drugs during clinical trials or patient therapy. (Aspirin, ReoPro®, Aggrenox®, Asasantin®, Pletal®, Plavix®, Persantine®, Integrelin®, Effient®, Ticlid)



The Platelet Aggregation Profiler, PAP-8E, is intended for use in clinical, research, university, biotechnology and pharmaceutical laboratories. The system measures the rate and extent of aggregation, agglutination, activation and inhibition reactions. Comprehensive results include area under the curve and area under the slope.

- Walk-Away Operation
- User-defined Test Templates and Protocols
- Minimal Patient Sample (225µL) Required
- Touch Screen Operation
- On Screen Directions and Procedures

A COMPLETE TEST SYSTEM
8 Test Channel Aggregometer
Electronic Pipette
Computer with Monitor
Software
Printer

Space-saving Footprint
Width: 35.56cm
Depth: 55.12cm

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PRODUCT APPLICATIONS

Clinical Laboratory

Perform Routine Aggregation Testing; Measure Ristocetin CoFactor Activity; Confirm Diagnosis of Heparin Induced Thrombocytopenia (HIT); Evaluate and Monitor Patients with Platelet Function Abnormalities; Manage Anti-Platelet Therapy; Pre- and Post-Operative Support of Left Ventricle Assist Device (LVAD) Patients.

Pharmaceutical Laboratory

Study Anti-Platelet Compounds; Examine Anti-Inflammatory or other Compounds, Leukocyte Aggregation and Platelet-Leukocyte Interactions; Micro-volume Capacity for Discovery, Pre-Clinical or Small Animal Model Studies.

Contract Research Organization (CROs)

Baseline and Monitor Platelet Function in Preliminary, as well as Blinded and
Non-Blinded Phase I, Phase II and Phase III Study Protocols.

Research Laboratory

Evaluate Platelet-Vascular Interactions; Study Biocompatibility Effects on Platelet Function; Examine Anti-Platelet and Lytic Agent Effects in Thrombotic Models or Events.

Veterinary Laboratory

Measure Ristocetin CoFactor Activity in Canine and Porcine Species; Diagnose Platelet Function Abnormalities in Animals; Measure Platelet Function in Animal Models.

A LEADER IN CLINICAL STUDIES

Because of their accuracy and reliable results Platelet Aggregation Profilers from Bio/Data Corporation have been selected for use in many significant studies including:

- Anti-Platelet Trialists Collaborative
- ARICA
- CAPTURE
- COMPARE
- EPIC
- EPISTENT
- GUSTO IV (aka SPEED)
- GUSTO V
- IMPACT II
- ISAR-REACT 3
- PCI CURE
- PLATO
- PURSUIT
- RESTORE
- TIMI 12
- TRITON

STANDARD COMPONENTS

- Computer & Touch Screen Monitor
- Pre-installed PAP-8E Software
- Printer (USA & Canada Only)
- Programmable Pipettor & Charging Stand
- Prism® Software
- Reagent Well Adapter Set

OPTIONAL COMPONENTS

- Barcode Scanner
- Extended Warranty

Product Specification:

Eight channel platelet aggregometer with four test modes:

- Routine Platelet Aggregation
- Ristocetin CoFactor Assay
- Special Platelet Aggregation
- Direct Test, no data input required

Test Wells: eight (stirred)

Activation Wells: eight (stirred)

Incubation Wells: eight (not stirred)

Temperature Control:

- Test and Incubation Blocks heated to 37° C ± 0.5°C
- Temperature is user adjustable

Digital Stir Speed Control:
0-1200 RPM

- Preset for standard tests (adjustable)
- Stir speed is user selectable for user defined tests

Test Samples: Platelet rich and platelet poor plasma, washed platelets, gel filtered platelets and leukocytes

Test Volume: 250µL

Sample Volume: 225µL

Reagent Volume: 25µL

Sensitivity: 50,000 platelets/mm3

Light Source: LED UV 430nm
Automatic range adjustment

Electrical Specifications:

Voltage selector switch 120/240 VAC, 50/60 Hz, 3A Isolated, grounded line required

Software:

- Three or four point standard curves for Ristocetin CoFactor Assay
- Routine Aggregation
- Trace filter, selectable; during and post test for each channel
- User defined test templates (test panels), saved for recall
- Walk-away operation – auto stop timers: countdown and elapsed time
- Data exporting direct to Prism® or Excel
- Screen captures to Windows clipboard
- Two level login security
- Data analysis: user selectable points and functions: primary and secondary slope, area under the curve, area under the slope, lag phase, shape change, disaggregation, max and final aggregation
- Database sorting and archiving
- Pre-loaded test parameters and user defined test protocols
- On screen help and on screen protocol methods manual

Dimensions:
Width: 14.0 inches / 35.6cm
Depth: 21.7 inches / 55.1cm
Height: 22.5 inches / 57.2cm
Weight: 45 pounds / 21.0 kg

PC Specifications:
Computer, Dell Optiplex™, Hard Drive 80GB minimum, Pentium® Processor, Microsoft Operating Software, 512MB RAM minimum, DVD/CD Read/Write 24x drive, Network: Ethernet, Ports: USB, Monitor, 15" Touch Screen Flat Panel Color LCD, Printer Color, Inkjet (USA & Canada only)

Limited Warranty

One year on PAP-8E parts, labour, and software. All other accessories or peripherals are covered under the manufacturer's warranty.

Safety Certifications:
The PAP-8E Analyser Module meets the following specifications: European Union Directive 98/79/EC In-vitro Diagnostic Medical Devices; European Union for each channel with audible alarm Electromagnetic Compatibility Directive 89/336/EEC; European Union Low Voltage Directive 73/23/EEC, European Standards: EN 61010-1:2001, Safety requirements for measurement control, and laboratory use, EN 61010-2 101:2002, Particular requirements for in-vitro diagnostic (IVD) medical equipment, EMC standards – EN61326, EN 61000-3-2, EN61000-3-3. The PAP-8E Analyser is designed to be in compliance with the following standards: UL 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements CAN/CSA C22.2 No. 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements. All accessory components have individual UL and CE certifications.

NOTE: The specifications for the PAP-8E and accessories are subject to change without notice.

CATALOGUE NUMBER

106077

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