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Press Release

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# WERFEN RECEIVES US FDA 510(K) CLEARANCE FOR GEM® HEMOCHRON™ 100 WHOLE BLOOD HEMOSTASIS TESTING SYSTEM

## — Rapid Hemostasis Testing and Advanced Connectivity at the Point of Care for Enhanced Efficiency and Patient Management—

**Bedford, MA, January 4, 2022**—Werfen today announced the 510(k) clearance of the GEM Hemochron 100 whole blood hemostasis system by the US Food and Drug Administration (FDA). Leveraging leading Hemochron technology, the GEM Hemochron 100 system, delivers fast, actionable activated clotting time (ACT) results in minutes, informing patient- management decisions and helping improve workflow at the point of care (POC). The GEM Hemochron 100 system is currently in clinical use in several European countries and will be commercialized in the US in early 2022.

Producing ACT results faster than traditional systems, the GEM Hemochron 100 system optimizes heparin dosing and enables rapid initiation of critical procedures for enhanced patient management. Cartridge-based technology reduces time and complexity of testing, as well as the need for training and maintenance. Additionally, an intuitive user interface and large touchscreen allow simple operation for workflow efficiency.

"In critical procedures, such as cardiac surgery, accuracy, speed and reliability of whole blood hemostasis testing to guide heparin therapy is paramount—and the GEM Hemochron 100 delivers," said Remo Tazzi, VP, Worldwide Marketing and Service, Hemostasis and Acute Care Diagnostics, at Werfen. "This allows clinicians to make informed patient management decisions at the point of care, helping improve patient outcomes in the Cardiovascular Operating Room and other acute care settings."

The GEM Hemochron 100 is designed for invasive procedures requiring heparin dose adjustment, where rapid and accurate ACT results are essential. Two ACT tests, ACT+ for moderate-high heparin doses (1–6 IU/mL) and ACT-LR for low-moderate (up to 2.5 IU/mL) heparin doses, offer testing flexibility in a variety of clinical settings, including the Cardiovascular Operating Room (CVOR), Cardiac Catheterization Lab, Electrophysiology Lab and Intensive Care Units.

Supporting current clinical practice guidelines, GEM Hemochron 100 ACT tests provide a maximally activated clotting time. This enables a shorter testing time, reduces susceptibility to hypothermia and artifacts, removes variability induced by hemodilution and correlates more closely to factor Xa activity, when compared to tests using a single activator.[1]

New integrated Wi-Fi capabilities in the GEM Hemochron 100 enable wireless, automatic, bidirectional data transmission and remote configuration. The GEM Hemochron 100 also offers an encrypted connection to ensure the security of patient data. GEMweb® Plus 500 Custom Connectivity simplifies and centralizes remote management of POC operators and GEM Hemochron 100 systems, as well as other Werfen and non-Werfen analyzers, throughout a hospital or hospital network.



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## Werfen Receives US FDA 510(k) Clearance for GEM Hemochron 100 Whole Blood Testing System

Hemochron technology has a long history of success in POC testing. First introduced in 1983, generations of Hemochron systems represent continuous improvements in efficiency. Today, the GEM Hemochron 100 offers the highest level of speed, simplicity and connectivity in whole blood hemostasis testing.

### About Werfen's Acute Care Diagnostics Portfolio

The GEM Hemochron 100 whole blood hemostasis testing system is part of Werfen's integrated and comprehensive Acute Care Diagnostics product portfolio—helping clinicians and laboratorians achieve better patient outcomes, lower total cost of care, assure compliance and improve operational efficiency in hospital acute care settings. For Whole Blood Hemostasis testing, the GEM Hemochron 100 system, ROTEM viscoelastic testing systems and VerifyNow™ platelet-reactivity testing system, inform key clinical decisions regarding transfusion, bleeding risk and anticoagulant dose adjustment during surgical and interventional procedures. For Blood Gas testing, the GEM Premier family, including GEM Premier 5000 and 3500 systems, and Avoximeter™ portable CO-Oximeters, simplify POC operations by automating key labor- and skill-intensive tasks, including quality management and system maintenance. From CVORs and Cardiac Catheterization Labs, to Intensive Care Units and Emergency Departments, whole-blood, cartridge-based systems with integrated data management solutions from Werfen help hospitals improve efficiency and enhance patient care.

**Reference**


1. Shore-Lesserson L, Baker RA, Ferraris VA, Greilich PE, Fitzgerald D, Roman P, Hammon JW. The Society of Thoracic Surgeons, The Society of Cardiovascular Anesthesiologists, and The American Society of ExtraCorporeal Technology: Clinical Practice Guidelines—Anticoagulation During Cardiopulmonary Bypass. *Ann Thorac Surg*: 2018;105:650-662.


Werfen (www.werfen.com), founded in 1966, is a worldwide developer, manufacturer and distributor of specialized diagnostic instruments, related reagents, automation workcells, and data management solutions for use primarily in hospitals and independent clinical laboratories. The Company's business lines include Hemostasis, Acute Care Diagnostics (ACD), Autoimmunity, and Original Equipment Manufacturing (OEM). Werfen's Hemostasis portfolio includes ACL TOP® Family 50 Series and ACL TOP Family Hemostasis Testing Systems, ACL AcuStar® system, ACL Elite® systems, HemoCell™ Specialized Lab Automation, HemoHub™ Intelligent Data Manager, along with the comprehensive line of HemosIL® assays. The ACD portfolio includes the GEM® Premier™ 5000 system with Intelligent Quality Management 2 (iQM®2), GEM Premier 3500 system with iQM, GEM Premier ChemSTAT™ system, GEMweb® Plus Custom Connectivity, ROTEM® viscoelastic testing systems, Hemochron™ systems, VerifyNow™ platelet function testing system, and Avoximeter™ CO-Oximeters. The Autoimmunity portfolio includes Aptiva®, BIO-FLASH®, NOVA View®, AUTOLoader and QUANTA-Lyser® 3000 systems, and QUANTA Link® data management solutions. The OEM business line offers services for end-to-end development and manufacturing of customized immunoassays and biomaterials for diagnostic companies.



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