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*If Veterans don't help Veterans, who will?*

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## FDA approves Nova Biomedical's next generation blood gas analyzer for point-of-care use

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Nova Biomedical's new generation blood gas analyzer, Stat Profile Prime, has been cleared by the U.S. Food and Drug Administration (FDA) for point-of-care (POC) use, allowing non-laboratory, POC personnel to perform bedside, critical care testing with lab-quality results.

The POC study submitted to the FDA to achieve this clearance included testing performed by 53 non-laboratory personnel in three POC settings. Method comparison and precision studies demonstrated that Stat Profile Prime is simple enough to use and provides lab-quality results in POC settings whether testing is performed by POC or laboratory personnel.

Stat Profile Prime's ZERØ™ maintenance cartridge technology consists of individual cartridges for sensors and calibrators. Each cartridge is maintenance free, ready to use, and easily replaced in seconds. This design optimizes the life of each cartridge; improves analyzer uptime; and eliminates the waste, downtime, and higher costs of older, combined sensor/calibrator cartridges.

Nova's MicroSensor Card technology contains biosensors for pH, PCO<sub>2</sub>, PO<sub>2</sub>, Na, K, iCa, Cl, Glu, Lac, and Hct. Credit card-sized, the MicroSensor Card is automatically calibrated and always ready to deliver a full 10-test profile in just 60 seconds. MicroSensor cards can be replaced in less than half the time of older cartridge systems, which can take more than one hour to calibrate and can remain unstable with drift, frequent re-calibrations, and reduced throughput for even longer periods of time. Stat Profile Prime's Clot Block™ sample flow path protects the MicroSensor Card from blockages and prolonged downtime caused by blood clots.

Compact, lightweight, and simple to operate with a color touchscreen, Stat Profile Prime may be used in a fixed location virtually anywhere in the hospital or operated on a mobile cart with a battery back-up. Stat Profile Prime ensures the highest quality and lab accuracy with automated, true liquid quality control and continuous electronic self-monitoring, saving time and labor.

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Source:

<http://www.novabio.us/>

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### Company Background

Incorporated in 1976 and based in Waltham, MA, Nova Biomedical is a world leader in the development and manufacturing of state-of-the-art, whole blood, point-of-care and critical care analyzers, and is one of the fastest growing in vitro diagnostic companies in the world.

Nova's whole blood biosensor technology is incorporated in products ranging from handheld meters for glucose self- and point-of-care testing to critical care whole blood analyzers designed for rapid measurement of over 20 analytes.

Nova employs over 1,000 people worldwide and has wholly owned subsidiaries located in Canada, France, Germany, Great Britain, Japan, and Taiwan. Certified by the International Organization for Standardization, Nova has manufacturing operations located in the U.S., Taiwan, and Brazil.