

FILAMATIC NEWS

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National Instrument Company is uniquely positioned to assist growing diagnostic and biotechnology companies that need to *upgrade fill/finish operations for plastic, microtube-style containers* from labor intensive laboratory/bench-top processes to automated production environments.



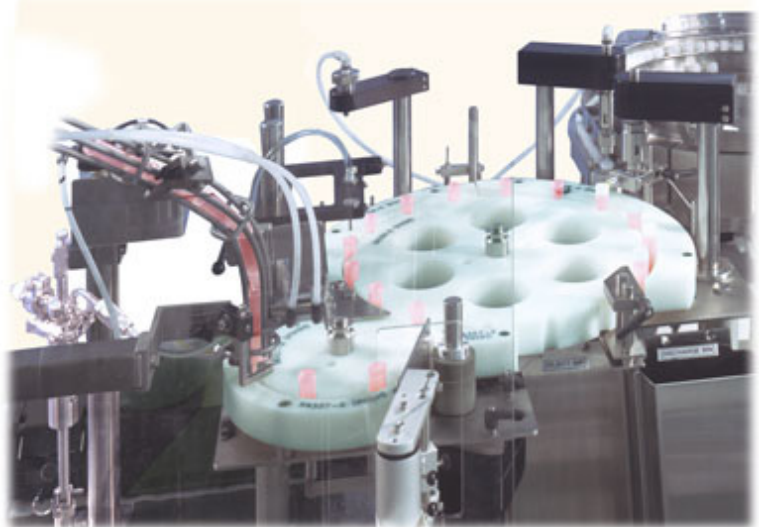
Baltimore, Maryland, December 2003 —
FOR IMMEDIATE RELEASE

FILAMATIC® Monobloc Systems offer solutions for companies looking to sort, feed, label, fill, and cap microtubes at rates of 25 to 85 containers per minute. This compact Monobloc system has an optional built in vertical flow HEPA module and is designed to fit within the small filling suites typically found at biotechnology facilities. All critical operations are servo controlled, and tool-less change parts/changeover processes further optimize its versatility and flexibility. Fill accuracies to $\pm 1/4\%$ can be achieved.

The need for automated fill/finish systems designed specifically for the diagnostic/biotechnology industry, as opposed to the adaptation of machinery designed primarily for glass vials and/or larger plastic bottles, is the result of continuing growth in the development of expensive, genetically engineered materials such as drug reference/ cell culture products and DNA/gene-based diagnostic products, reagents, and tests. These products are typically shear-sensitive liquids that are filled into plastic microvials, microcentrifuge tubes, and cryogenic/ cell culture tubes in volumes ranging from 10 μ l to 5 ml. The plastic containers (1) are very small in size (2) are shipped to end users in bulk, (3) are not free standing (i.e. cannot be conveyed), and (4) require the application/installation of screw or plug-type closures.



PLASTIC MICROTUBE STYLE CONTAINERS



MICROTUBE FILL / FINISH MONOBLOC FRONT VIEW

Continued

A recent development in the biotechnology industry is the availability of pre-capped (closed) microtubes that have been pre-sterilized via gamma radiation. **National Instrument Company now offers a Compact Monobloc System that is the industry's first completely automated production system for handling pre-capped/pre-sterilized microtubes.** The system possesses a compact overall footprint, including the HEPA filtration module mounted on top of the interlocked safety enclosure. The monobloc system incorporates a unique GMP design that, *at a single operating station*, provides for the removal of the screw cap, the filling of the microtube, and the re-application of the original cap. This multi-functional, single station configuration reduces the possibility of product contamination by eliminating multiple handling of the screw cap.

The small fill volumes and gentle product handling required in microvial production are achieved by a filling process utilizing either a servo-driven **FILAMATIC®** type DUS positive displacement filling unit, or other third-party volumetric or peristaltic pumps.

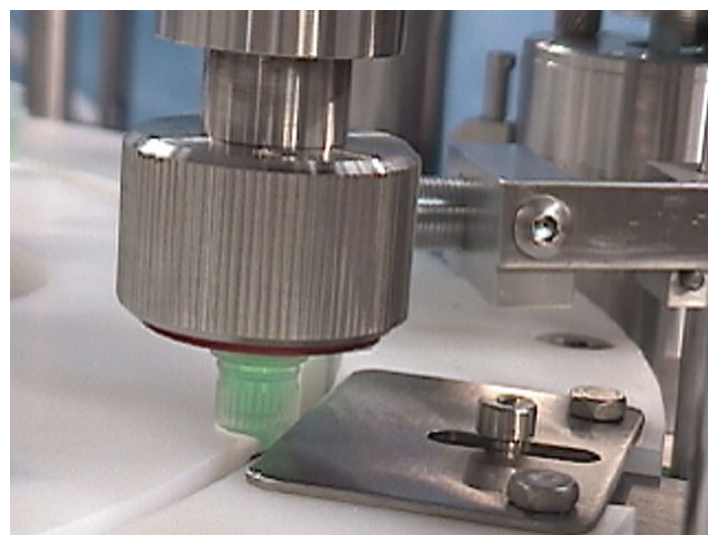
Menu-driven programs accessed via a touchscreen located on an operator interface are used to electronically adjust operating parameters such as fill volume and cap torque. The touchscreen interface eliminates the need for manual adjustments during the set-up and changeover process.

All **FILAMATIC®** monobloc systems include safety guarding to prevent injury to operators and maintenance personnel. The safety guarding is interlocked such that the monobloc system will not operate if one or more guard doors are opened.

Comprehensive IQ/OQ protocol and GAMP documentation packages are also available.



MICROTUBE FILL / FINISH MONOBLOC SIDE VIEW
(Shown with DUS with medical grade diaphragm and optional peristaltic fill head.)



SERVO TORQUEING MICROTUBE SCREW CAP

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