Health problem addressed
Perform tests on whole blood, serum, plasma, or urine samples to determine concentrations of analytes (e.g., cholesterol, electrolytes, glucose, calcium), to provide certain hematology values (e.g., hemoglobin concentrations, prothrombin times), and to assay certain therapeutic drugs (e.g., theophylline), which helps diagnose and treat numerous diseases, including diabetes, cancer, HIV, STD, hepatitis, kidney conditions, fertility, and thyroid problems.

Product description
Chemistry analyzers can be benchtop devices or placed on a cart; others are handheld. Reagents may be stored within the analyzer or reagent strips may be inserted into a slot. External components typically include a sample slot or tray and a keypad or touchscreen, bar-code scanner, display, and ports to connect to a printer and/or computer. Internal components typically include a light source and photometer or a series of electrodes to analyze the sample.

Principles of operation
Samples are applied to a strip or tube containing reagents, which produces a chemical reaction. A light source transmits a beam of light onto the sample. Some analyzers use light-emitting diodes (LEDs) or fiberoptic lights to produce monochromatic light. The amount of reflected or absorbed light is measured by a photodetector. Some analyzers use electrodes instead of photometers to measure analyte concentrations in solution. Solid-state electrodes covered by a selectively permeable membrane allow passage of only the analyte being measured. The electrode registers changes in the electrical current passing through it; this current is proportional to the concentration of analyte in solution. The analyzer then calculates the presence and concentration of analytes and/or drugs and displays the results.

Operating steps
• Samples are inserted in a slot or loaded onto a tray.
• Patient information and tests ordered are entered using a keypad, touchscreen, or bar-code scanner.
• If necessary, reagents are loaded.
• After the required test(s) are run, the results can be displayed on-screen, printed out, stored in the analyzer’s internal memory, transferred to a computer, and/or interfaced into EMR.

Reported problems
Operators should be aware of the risk of exposure to potentially infectious bloodborne pathogens during testing procedures and should use universal precautions, including wearing gloves, face shields or masks, and gowns.

Use and maintenance
User(s): Physician or nurse, laboratory technician
Maintenance: Biomedical engineering staff and/or service contract with the manufacturer or third-party organization
Training: Manufacturer-provided training, manual

Environment of use
Settings of use: Hospital; clinic; physician office; clinical laboratory
Requirements: Line power, biohazard disposal

Product specifications
Approx. dimensions (mm): 150 x 240 x 350 handheld units; 450 x 400 x 180 benchtop units
Approx. weight (kg): 4.5 handheld units; 14 benchtop units
Consumables: Reagents, reaction cuvettes, sample strips
Price range (USD): 2,000-5,000 (3,500 typical) for handheld units; 3,000-6,500 (4,500 typical) for benchtop units
Typical product life time: 7 years
Shelf life (consumables): 1-2 years reagents

Types and variations
• Handheld models analyze one sample at a time
• Benchtop models may analyze multiple samples simultaneously
• Specialized purpose models may measure only one analyte (e.g., cholesterol analyzers)