Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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Impressive Progress: Implement the Ecological Advantages of CLINITEK Status+ Analyzer
Get Convenient Point-of-Care Urinalysis with Improved Clinical Information

The CLINITEK Status+ Analyzer is the latest addition to the CLINITEK® family, the most widely used urinalysis brand worldwide. The analyzer enhances confidence in clinical decisions and respects the environment.

- **Energy Efficiency**  
  36% decrease in energy consumption compared with previous version—CLINITEK Status Analyzer

- **Documentation of Product Substances**  
  All substances contained in the product and its packaging are documented.

- **High Recyclable Content**  
  Nearly 99% of components can be recycled for materials or energy.

- **Product Take-Back**  
  Product exchange program available.

- **Environmental Product Declaration**  
  Available for download via the Internet at www.siemens.com/epd

**System Overview**

The CLINITEK Status+ Analyzer is a CLIA-waived, point-of-care urinalysis analyzer that automatically performs and reads tests and provides improved clinical information when using new urinalysis test strips by Siemens Healthcare Diagnostics.

**Ease of Use/Convenience**

- Simple, intuitive touchscreen operation
- Load test—analyzer does the rest
- Fast results—in-office test results in about 1 minute
- Automatic printed report—no manual transcription needed

**Improved Data Integrity**

- New analyzer, along with patented test-strip technology, enables automatic checks (Auto-Checks) for:
  - Identification of Siemens strip type
  - Sample interference notes if common sample interferences are detected
  - Automatic error messages if strip has been exposed to humidity
- Removes subjectivity of visually read results

**Complete Point-of-Care Test Portfolio**

- **MULTISTIX® 10SG** is the most widely used urinalysis test strip for routine testing
- Albumin-to-creatinine ratio automatically calculated with CLINITEK Microalbumin 2 and CLINITEK Microalbumin 9 strips for early detection of kidney disease in patients with diabetes
- Analyzer accommodates cassette for CLINITEST® hCG testing for pregnancy

**Future Ready**

- Upgrade kits are available:
  - For analyzer connectivity to LIS/HIS, EMR (electronic medical record), or data management software
  - For bar-code data entry of: operator ID, patient ID, lot number, and expiration date of Quality Control material

1. Availability dependent on strip type. Feature not available in the U.S.
2. Available only with test strips that have the leukocyte pad.
Environmental Management System

Our environmental, health, and safety management system complies with ISO 14001 and OHSAS 18001 and helps us put our policy into practice.

In 2012, our global operations were certified by third-party registrar SGS as conforming to ISO 14001 and OHSAS 18001.

For more information about our environmental, health, and safety management system, go to www.siemens.com/healthcare-ehs.

Environmental Product Design

Siemens Healthcare considers environmental factors during all phases of the product lifecycle, including material supply, production/delivery, use/maintenance, and end of life. Our product design procedure fulfills the requirements of IEC 60601-1-9:2007 “Environmentally conscious design of medical electrical equipment.”

This standard supports the effort to improve the environmental performance of our products.

Identification of Product Components

The CLINITEK Status+ Analyzer is a small, lightweight, portable device built primarily from plastics and metals that can be recycled almost completely for materials or energy.

Material Supply

From natural resources to delivery of semi-finished products

Material Supply Production/Delivery

From production of components to operation startup by the customer

Use/Maintenance

Includes daily use by our customers as well as maintenance

End of Life

From disassembly at the customer site through material and energy recycling

Cumulative Energy Demand

Energy consumption is the most important environmental consideration for medical devices. This is why we use the Cumulative Energy Demand analysis to assess environmental performance. Cumulative Energy Demand is the total primary energy that is necessary to produce, use, and dispose of a device—including all transportation.

For the majority of products, most of the environmental impact stems from energy use during the use phase.

A comparative analysis of the primary energy demand during device use† indicated a 36% decrease in energy consumption between CLINITEK Status+ and the previous analyzer version (CLINITEK Status).

Unlike material supply, manufacturing, and end-of-life phases, the environmental impact of the use phase directly impacts our customers. At Siemens, we look constantly for ways to help our customers reduce their environmental burden.

Primary Energy Over Lifecycle Phases

Product Take-Back

Most of the materials used to produce the CLINITEK Status+ Analyzer are recyclable: 98% (by weight) can be materially and 1.8% energetically recycled.

At Siemens Healthcare, our product take-back program ensures that we address the environmental aspects of our products—even at the end of life. We also recycle components for material and energy value.
CLINITEK Status+ Analyzer Specifications, Maintenance, and Disposal

CLINITEK Status+ Analyzer Specifications

Intended Use
The CLINITEK Status+ Analyzer is a point-of-care urinalysis analyzer designed to read Siemens Healthcare Diagnostics urine test strips and CLINITEST® hCG cassettes.

Semiquantitative Tests Measured
Routine urine tests: albumin, bilirubin, creatinine, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen.

Kidney Disease Tests
Albumin-to-creatinine ratio

Pregnancy Test
Human chorionic gonadotropin (hCG)

User Interface
Touchscreen

Computer Interface
Unidirectional via serial port (RS232)

Data Entry
Onboard touchscreen

Power Requirements
Electrical rating 100–240 VAC, 50–60 Hz (with in-line lead)
Battery operation 6 AA batteries, nonrechargeable

Dimensions/Weight
Depth: 10.70 in. (27.2 cm)
Width: 6.70 in. (17.1 cm)
Height: 6.20 in. (15.8 cm)
Weight: 3.65 lbs (1.66 kg)

Calibration
Automatic, self-calibrating

Compliance
CLIA-waived, CE-marked, UL, EMC

New Features
Test results 950
Operator IDs 700
Automatic Checks (Auto-Checks)
Identification of strip type
Humidity exposure tested on every strip with leukocyte pad
Common sample-interference check available depending upon strip type (not available in the U.S.)

A Broad Menu for Point-of-Care Urinalysis Testing on One Analyzer

<table>
<thead>
<tr>
<th>Product</th>
<th>Tests</th>
<th>Clinical Utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>MULTISTIX® 10SG Reagent Strips</td>
<td>Reliable frontline test for detection of a broad range of conditions</td>
<td>Routine testing</td>
</tr>
<tr>
<td>CLINITEK® Microalbumin 2 and CLINITEK® Microalbumin 9 Urinalysis Strips</td>
<td>Albumin-to-creatinine ratio test</td>
<td>Detection of early kidney disease for patients with confirmed diabetes</td>
</tr>
<tr>
<td>MULTISTIX PRO® Reagent Strips</td>
<td>Protein-to-creatinine ratio test</td>
<td>Detection of early kidney disease for high-risk patients</td>
</tr>
<tr>
<td>CLINITEST® hCG Pregnancy Test</td>
<td>Qualitative hCG test</td>
<td>Pregnancy testing</td>
</tr>
</tbody>
</table>

Operating Data

- Temperature Range: 18°C - 30°C (64°F - 86°F)
- Humidity Range: 18-80% Relative Humidity
- Energy consumption:
  - Basic Load: 5 W
  - Full Load: 7 W

Cleaning

Incompatible Cleaning Processes
- Total device
- Restrictions for particular device components
- Organic solvents
- Peroxide chamber solution immersion
- Organic solvents

List of Incompatible Substance Classes
- Total device
- Restrictions for particular device components
- Organic solvents
- Organic solvents

Suitability of the Device
- For sterile areas
- Product is not sterile. Outer surfaces may be sterilized with 10,000 ppm hypochlorite.

Disposal/Substance Information
- End-of-Life Concept
- Recycling Information
- List of Hazardous Substances
- CLINITEST® hCG Pregnancy Test

Further Ecologically Relevant Information
- Elements of Instruction are Recommendations for:
  - Saving Energy
  - Efficient Cleaning
  - Efficient Use of Consumables

Elements of Instruction

4. CLINITEK MA 9 not available for sale in the U.S. Product availability varies by country.
5. Product availability varies by country.
6. Average value for energy consumption when device is in operation.
7. Max power under load (when printing).