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Environmental  
Product  
Declaration

[www.siemens.com/clinitekstatus](http://www.siemens.com/clinitekstatus)

# CLINITEK Status+ Analyzer

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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](http://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<sup>1</sup>
  - Automatic error messages if strip has been exposed to humidity<sup>2</sup>
- 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 CLINITEK® 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.

**Printed Record**  
Helps to avoid transcription errors

**Detects Common Sample Interference<sup>3</sup>**  
Provides printed comment if certain interferences are detected that could compromise results

**Auto-Checks for Humidity**  
Checks each test strip for overexposure to humidity. If detected, reporting is prevented<sup>2</sup>



**Get Connected**  
Connectivity is ready when you are with simple upgrade kit



**Comprehensive Urine Test Menu**  
Includes hCG pregnancy testing



**Automatic Strip Identification**  
Eliminates the need for operator to enter strip configuration

The easy-to-use, automated analyzer delivers quick, accurate, reliable results. And new advanced technology performs automated quality checks on every test for more precise decision making.

3. Feature not available in the U.S.

# Form Follows Function... With a Smaller Footprint

## 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](http://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.

**Material Supply**  
From natural resources to delivery of semi-finished products

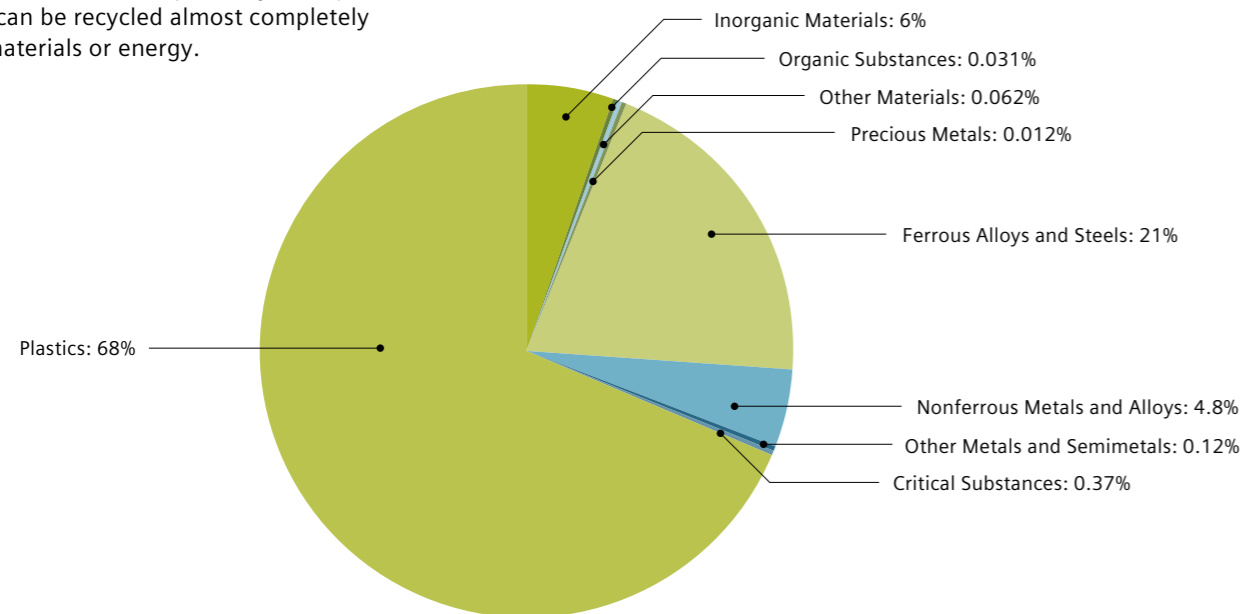
**Material Supply Production/Delivery**  
From production of components to operation startup by the customer

**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

## 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.



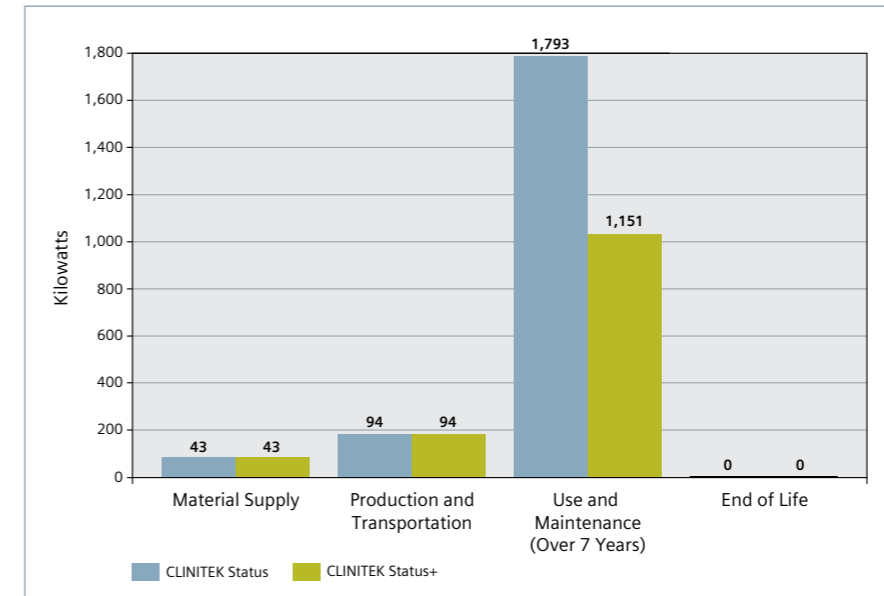
# Less Is More... More or Less

## Cumulative Energy Demand

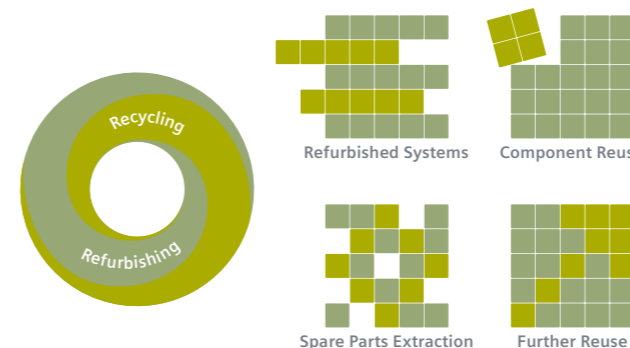
Energy consumption is the most important environmental consideration for medical devices. This is why we use the Cumulative Energy Demand analysis to assess environmental performance. Cumulative Energy Demand is the total primary energy\* that is necessary to produce, use, and dispose of a device—including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



\*Primary energy is the energy contained in natural resources prior to undergoing any man-made conversions (e.g., oil, solar).  
†The energy for use was based on 24-hour operation, year-round, over an estimated 7-year lifetime (on average) of the device. Material supply, production and transportation, and maintenance were kept equal for both analyzers. End-of-life options were not considered in the study due to regional differences in product take-back programs.



## 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 (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

#### Memory

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.)

‡Available only when using Siemens test strips with ID or color bands.



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

Product	Tests	Clinical Utility
MULTISTIX® 10SG Reagent Strips	Reliable frontline test for detection of a broad range of conditions	Routine testing
CLINITEK® Microalbumin 2 and CLINITEK® Microalbumin 9 <sup>4</sup> Urinalysis Strips	Albumin-to-creatinine ratio test	Detection of early kidney disease for patients with confirmed diabetes
MULTISTIX PRO® Reagent Strips <sup>5</sup>	Protein-to-creatinine ratio test	Detection of early kidney disease for high-risk patients
CLINITEST® hCG Pregnancy Test	Qualitative hCG test	Pregnancy testing

Operating Data	
Temperature Range	18°C - 30°C (64°F - 86°F)
Humidity Range	18-80% Relative Humidity
Energy consumption:	
– Basic Load <sup>6</sup>	5 W
– Full Load <sup>7</sup>	7 W

Disposal/Substance Information	Yes	No
End-of-Life Concept	•	
Recycling Information	•	
List of Hazardous Substances	•	
CLINITEST® hCG Pregnancy Test	•	

Further Ecologically Relevant Information	Yes	No
<b>Elements of Instruction are Recommendations for:</b>		
Saving Energy	•	
Efficient Cleaning	•	
Efficient Use of Consumables	•	

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

Cleaning	
<b>Incompatible Cleaning Processes</b> – Total device	– Organic solvents peroxide chamber solution immersion – Organic solvents
– Restrictions for particular device components	– Organic solvents
<b>List of Incompatible Substance Classes</b> – Total device – Restrictions for particular device components	– Organic solvents – Organic solvents
<b>Suitability of the Device</b> – For sterile areas	– Product is not sterile. Outer surfaces may be sterilized with 10,000 ppm hypochlorite.