

Cepheid - SmartCycler System



GENERAL DESCRIPTION:

The Cepheid SmartSystem™ is potentially the most sensitive real-time PCR testing platform available on the market. With up to 96 individually programmable reaction sites, it is one of today's most flexible, easy-to-use systems. No other system is designed for complete portability in the field. The SmartCycler System is highly robust and compact, with no moving components—ideally suited for mobile use in field-testing applications. By automating the entire amplification and detection process, the SmartCycler System can deliver highly accurate and consistent test results from prepared biological samples in 20–40 minutes. Flexible and Expandable Cepheid's SmartCycler® instrument is the only random access, modular real-time PCR instrument on the market with up to 96 sites that can each run a different protocol.



Installation of the SmartCycler System is plug-and-play, and system expansion only requires an additional USB connection. Fast With the SmartCycler System, you can optimize PCR denaturation, annealing and extension temperatures and times in a single run. The SmartCycler System can deliver results in less than half the time of a 96-well plate instrument. High Throughput Two SmartCycler instruments can process an equal or greater number of samples than a 96 well instrument in a single day. Assay Optimization Made Easy Increase Flexibility - random access accommodates varied cycling conditions, with variable amplicon lengths, cycling times, and assay design; Increasing Robustness, Decreasing time to results. Mobile Heavy-duty airline-safe transport case and laptop configuration is available for the SmartCycler System, making it ideal for field work.

TECHNICAL DESCRIPTION:

The Cepheid SmartSystem™ is potentially the most sensitive real-time PCR testing platform available on the market. With up to 96 individually programmable reaction sites, it is one of today's most flexible, easy-to-use systems. No other system is designed for complete portability in the field. The SmartCycler System is highly robust and compact, with no moving components—ideally suited for mobile use in field-testing applications. By automating the entire amplification and detection process, the SmartCycler System can deliver highly accurate and consistent test results from prepared biological samples in 20–40 minutes.

CONTACT INFORMATION

Cepheid
 904 Caribbean Drive
 Sunnyvale, CA 94089
 POC: Chinmay Sheth

COST

- \$34,995/system
- \$3/analysis

Tier Selection

Final tier assignment is based on overall product score.

- Top Tier
- ◐ Second Tier
- Third Tier
- ◑ Fourth Tier
- Bottom Tier

RANKINGS

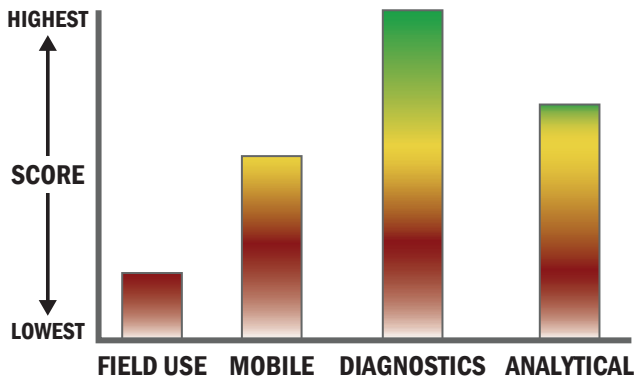
	Biological	Chemical	Radiological
FIELD USE System	○	N/A	N/A
MOBILE Laboratory	◐	N/A	N/A
DIAGNOSTIC Laboratory	●	N/A	N/A
ANALYTICAL Laboratory	●	N/A	N/A

Survey Source

Vendor Supplied Information

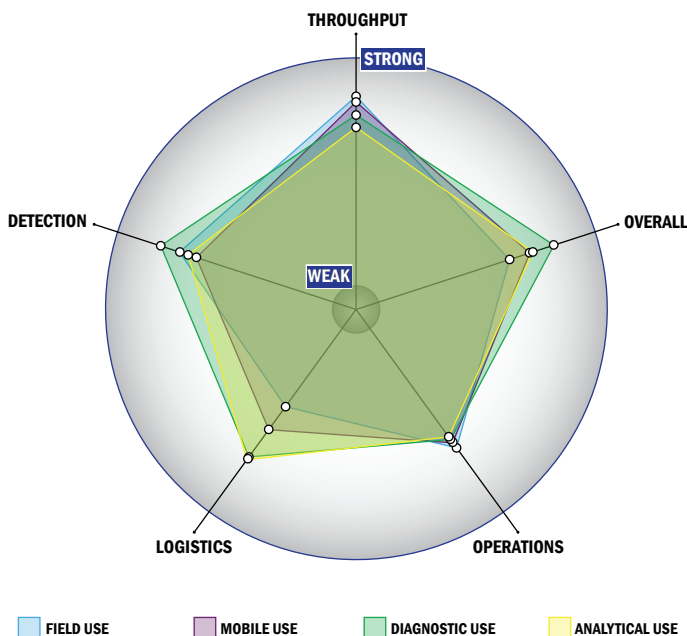
Scoring Analysis

System scores are compared across the four scenarios and ranked from highest to lowest.



Impact Chart

The Impact Chart is a spider graph representing specific categories and designed to give the reader a visual depiction of how a particular system is expected to operate across the four different scenarios. The score for each of the seven categories is presented as the percentage of the total possible score. Higher category scores extend the spokes of a graphic toward the outer edge of the chart. The area graphed for each of the four scenarios relates to how well the system performed in that scenario. Graphics for each of the four scenarios are super-imposed for ease of comparison.



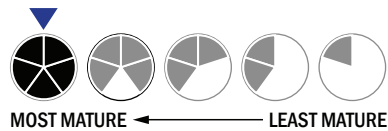
Evaluation Criteria

Throughput:

- Between 30 and 60 minutes for detection
- Multiple samples, multiple tests/sample per run
- 349-96 samples every 2 hours
- The system or device is currently fully automated
- Device or system is designed for a single use
- 0-1 solutions, buffer, eluents, and/or reagents
- 2 components
- No set-up of the system is required
- 1-2 steps are required for detection

Logistics:

- An afternoon of training and some technical skills required
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- This system is not capable of transmitting data
- System or device has 110V electrical requirement
- <1 Hour battery life



Operations:

- Can be used from 4 °C to 41 °C
- Components must be stored at room temperature (27 °C)
- Performance is not influenced by relative humidity
- Between 6 months and 1 year shelf life
- Results can be viewed in real-time
- The system is not capable of autonomy
- The system software is open and available for modification
- The system hardware is closed and not available for modification

Detection:

- System currently has 510k clearance
- System currently has FDA approval
- Less than 100 µL
- Excellent specificity. System has occasional false alarms under certain conditions (<2%)
- 100-1,000 CFU per mL
- 100-1,000 PFU per mL
- 10-100 ng per mL
- Fully automated spore lysis

