Hello! It seems like the document you've provided contains information about bedside glucose testing systems, but I'm unable to read it naturally due to its format. It appears to be a table with various aspects of glucose testing systems, but the text is not clearly readable. If you have any specific questions or need help understanding certain parts of the document, feel free to ask! I'm here to help. 😊
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Professional or home use</td>
<td>professional</td>
<td>professional</td>
<td>professional</td>
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<tr>
<td>Total units sold in U.S./Total units sold outside U.S.</td>
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<tr>
<td>No. of contracts for product signed in 2019</td>
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<tr>
<td>Dimensions (H × W × D/Weight)</td>
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<tr>
<td>Analytical method or technology or enzyme system used</td>
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</tr>
<tr>
<td>No. of disposable reagent system units per basic package</td>
<td>50 or 100</td>
<td>50 test strips per vial</td>
<td>50 test strips per vial</td>
</tr>
<tr>
<td>Disposable unit shelf life</td>
<td>18 months</td>
<td>24 months from date of manufacture</td>
<td>24 months from date of manufacture</td>
</tr>
<tr>
<td>Reagent unit storage requirements</td>
<td>34~°86°F</td>
<td>room temperature</td>
<td>room temperature</td>
</tr>
<tr>
<td>Distinguishing features (supplied by company)</td>
<td>---</td>
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</tr>
<tr>
<td>How results are displayed</td>
<td>---</td>
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<tr>
<td>Specimen types</td>
<td>---</td>
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<tr>
<td>Sampling techniques</td>
<td>---</td>
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</tr>
<tr>
<td>Minimum specimen volume required</td>
<td>0.5 mL</td>
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<tr>
<td>Suitable for samples from well neonates/Sick neonates</td>
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<tr>
<td>Time from sample introduction to result availability</td>
<td>5 seconds</td>
<td>6 seconds</td>
<td>6 seconds</td>
</tr>
<tr>
<td>Batteries used/No. used/Average life of one set of batteries</td>
<td>3v lithium (disposable, type CR2032)/2/1,000 tests</td>
<td>AAA/2/minimum 600 tests</td>
<td>AAA/2/minimum 600 tests</td>
</tr>
<tr>
<td>Average expected life of device</td>
<td>3 years</td>
<td>&gt;5 years</td>
<td>&gt;5 years</td>
</tr>
<tr>
<td>Device warranty</td>
<td>3 years</td>
<td>(optional 5-year extended warranty) meter replacement/yes</td>
<td>(optional 5-year extended warranty) meter replacement/yes</td>
</tr>
<tr>
<td>Service options/Loaners provided</td>
<td>---</td>
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</tr>
<tr>
<td>User list or user group</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Toll-free No. for customer questions/hours of operation Training and certification program/No. of training days provided</td>
<td>800-818-8877/24 hours, 7 days, yes/one on site</td>
<td>800-458-5813/24 hours, 7 days, all year/yes/defined during implementation plan</td>
<td>800-458-5813/24 hours, 7 days, all year/yes/defined during implementation plan</td>
</tr>
<tr>
<td>Internal QC recommended or required</td>
<td>control solution testing</td>
<td>CLIA requirements, two levels per day or per hospital policy</td>
<td>CLIA requirements, two levels per day or per hospital policy</td>
</tr>
<tr>
<td>Accuracy</td>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>• Compared with reference method or device</td>
<td>YSI model 2300 glucose analyzer</td>
<td>&gt;97% versus IDMS-traceable laboratory reference method</td>
<td>&gt;97% versus IDMS-traceable laboratory reference method</td>
</tr>
<tr>
<td>Precision</td>
<td>---</td>
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</tr>
<tr>
<td>• Compared with reference method or device</td>
<td>YSI model 2300 glucose analyzer</td>
<td>---</td>
<td>---</td>
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<tr>
<td>Linear range</td>
<td>20–600 mg/dL</td>
<td>10–600 mg/dL (0.5–33.3 mmol/L)</td>
<td>10–600 mg/dL (0.5–33.3 mmol/L)</td>
</tr>
<tr>
<td>Suggested dynamic or measurement range</td>
<td>20–600 mg/dL</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Known interferences</td>
<td>---</td>
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<tr>
<td>High-altitude interference</td>
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<tr>
<td>Restrictions based on hematocrit</td>
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<tr>
<td>Electronic and optical function checks</td>
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<tr>
<td>Sample quantity checks</td>
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<tr>
<td>When auto lock or shutdown occurs</td>
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<tr>
<td>User can define QC lockout intervals/QC lockout can be circumvented</td>
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</tr>
<tr>
<td>Information for which device supports barcode scanning Method of analyst ID/ID required Internal memory size</td>
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<td>---</td>
<td>---</td>
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<tr>
<td>Maximum No. of patient results stored</td>
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<tr>
<td>Meter connections for information transfer</td>
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<tr>
<td>How meters are connected to external system to upload results Information contained in transmission to external system</td>
<td>---</td>
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<tr>
<td>Hardware and software for data-management system</td>
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<tr>
<td>Information downloaded from DMS to meter</td>
<td>---</td>
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</tr>
<tr>
<td>Lifes/HSs to which system is connected (live install) using:</td>
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<tr>
<td>LOINC can be used to identify tests when communicating with LIS</td>
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<td>---</td>
</tr>
<tr>
<td>Distincting features (supplied by company)</td>
<td>optimized readout display: large, thick numbers are intended to improve readability</td>
<td>only meter FDA cleared for use with all sample types, including capillary, in critically ill patients</td>
<td>only meter FDA cleared for use with all sample types, including capillary, in critically ill patients</td>
</tr>
<tr>
<td>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</td>
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</tr>
</tbody>
</table>

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.
Part 3 of 3
See captodayonline.com/bedside-glucose for an interactive product comparison or PDF of guide

Name of instrument/First year sold
Roche Diagnostics
Excellin II System 2012

Professional or home use
—

Total units sold in U.S./Total units sold outside U.S.
—

No. of contracts for product signed in 2019
—

Dimensions (H × W × D)/Weight
385 × 965 × 748 mm/12.24 oz (347 g)

Analytical method or technology or enzyme system used
electrochemical (AC/DC), mutant variant quinoprotein

No. of disposable reagent system units per basic package
50 strips per vial

Disposable units shelf life
18 months

Reagent unit storage requirements
39°–86°F (4°–30°C)

Digital readout character size/Keypad input capability
test results are 48-point font/menu selection, numeric, alphabetic

How results are displayed
plasma equivalent values

Specimen types
whole blood

Sampling techniques
—

Minimum specimen volume required
0.6 μL

Suitable for samples from well neonatal/Sick neonates
yes

Time from sample introduction to result availability
5 seconds

Batteries used/No. used/Average life of one set of batteries
—

Average expected life of device
5 years

Device warranty
1 year or contract term

Service options/Loaners provided
replacement/no

Toll-free No. for customer questions/Hours of operation
800-440-3638/24 hours, 7 days, all year

Internal QC recommended or required
follow facility policy for control testing intervals

Training and certification program/No. of training days provided
yes/defined during implementation planning

User list or user group
—

Electronic and optical function checks
150 integrity checks, including variation in hematocrit,

High-altitude interference
none, up to 10,000 feet

Precision

controls: low SD=1.2 mg/dL, mid SD=2.2, high SD=4.6;

Accuracy

capillary: r=0.993, venous: r=0.995; arterial: r=0.976

• Compared with what reference method or device

• Compared with what reference method or device

Linear range
10–600 mg/dL

Suggested dynamic or measurement range
10–600 mg/dL

Contraindications
yes (per labeling)

Known interferences
yes (per labeling)

High-altitude interference
none, up to 10,000 feet

Restrictions based on hematocrit
yes, hematocrit range: 10–65%

Electronic and optical function checks
150 integrity checks, including variation in hematocrit,

Sample quantity checks
—

When auto lock or shutdown occurs
—

User can define QC lockout intervals/QC lockout can be circumvented
—

Information for which device supports barcode scanning
—

Method of analyst ID/ID required
—

Internal memory size
300 predefined comments

Maximum No. of patient results stored
—

Meter connections for information transfer
—

How meters are connected to external system to upload results
data-management system, which connects to LIS/HIS

Information contained in transmission to external system
direct serial, hospital network, real-time wireless (RF)

Hardware and software for data-management system
Roche Cobas IT 1000 application for connection to third-party DMS, including Telcor QML, Abbott RALS

Information downloaded from DMS to meter
strip lot numbers, valid control values, valid operator IDs, patient IDs, meter configuration, linearity lot numbers and values, comments

Info/HIS to which system is connected (live installs) using:
Roche Cobas IT 1000 application for connection to third-party DMS, including Telcor QML, Abbott RALS

• Screen animation/Screen scraping

• Standard HL7 interface

• Proprietary protocol interface

Use 3rd-party interfacing tool or engine for LIS or HIS interfaces
yes, Telcor QML or Abbott RALS

LOINC can be used to identify tests when communicating with LIS
yes

Distinguishing features (supplied by company)
• 150 individual quality checks are conducted prior to measuring the glucose concentration

• patented dual-current AC/DC meter technology checks a range of variables including compensation for hematocrit

• adjustable workflow option for isolation patients: live 24/7/365 customer care service and support

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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Estimating measurement uncertainty
Christopher M. Lehman, MD
William J. Castellani, MD
Cordella E. Sever, MD

Quantifying the uncertainty of the laboratory measurements that we report to clinicians is an important quality tool and can assist clinicians in interpreting results. In particular, evaluating patient results over time (longitudinal observation) requires determining whether a result is truly different from a previous result or whether the difference could be attributable to measurement uncertainty. Traditionally, chemistry laboratories have calculated various levels of assay imprecision (within lab, total) to satisfy CLIA validation/verification requirements and to monitor assay quality. These imprecision calculations serve as estimates of measurement uncertainty (MU). Estimation of MU outside the chemistry laboratory (hematology, immunology, microbiology) is not as common.

The CAP administers a voluntary accreditation program (CAP 15189) according to the requirements of the Quality Management Standard from the International Organization for Standardization for Standardization ISO 15189:2012 Medical Laboratories—Requirements for Quality and Competence that requires that MU information be made available to laboratory users on request. This requires calculation of MU for all reported quantitative results, as well as results that are qualitative but based on quantitative results (drug screens, for example). MU must also be estimated for results that are reported as calculations (for example, urine albumin/creatinine and eGFR). MU estimation for these results requires combining the MU estimates for the individual components of the reported result, a calculation that may be unfamiliar to many technologists and technicians working in the laboratory.

Recently, ISO published ISO/Technical Specification 20914:2019 Medical Laboratories—Practical Guidance for the Estimation of Measurement Uncertainty, which provides background explanation of MU estimation, definitions of relevant terminology, and a structured format for calculating MU with worked examples for chemistry, immunology, coagulation, hematology, molecular, and microbiology analytes. Imprecision calculations that form the basis for the MU estimates will be familiar to clinical chemists but perhaps less familiar to other disciplines. The use of standardized MU vernacular, which is uncommon in U.S. clinical laboratories, will require some getting used to, even for clinical chemists.

ISO/TS 20914:2019 was developed as a “technical specification” and therefore implementation of the document is not required of ISO-15189–accredited laboratories, including those laboratories participating in the CAP program. However, the document should be helpful to laboratories accredited to the ISO 15189 standard in meeting the MU estimation requirement, and it can also be used by any laboratory that wishes to further evaluate its results and the variation that may be seen (and reported) over time.

Dr. Lehman, of ARUP Laboratories, is chair of the CAP Standards Committee. Dr. Castellani, of Penn State Hershey College of Medicine, is a member of the committee, and Dr. Sever, of Presbyterian Hospital in Albuquerque, NM, is vice chair.