

## Functional-Performance-Specification

General Equipment Name: Osmometer Automated Multisample Model A20 or equal

### Required Individual Line Items & Quantity of Items

- (1 each) Osmometer Automated Multi-Sampler
- (2 each) Maintenance Manuals (CD, PDF or Word)
- (2 each) User Manuals
- (1 each) Cleaning Instructions for all equipment, supplies and accessories

### Description & Salient Characteristics

Freezing point depression for osmolality determination. Positive sample bar code identity, easy autosampling system with liquid detection, bidirectional communication, optional duplicate sample testing setup, retrievable patient results and on board Quality Control. Table top model with acceptable accuracy and precision, calibration and QC materials for following required guidelines. For osmolality measurement of solutions using freezing point depression; Automated; Multi sample; Designed to process a 20uL sample; Test time: 60 sec.; 20.5 x 23.6 x 38.1 inches.

### Hardware Features:

Operating conditions: 18°C to 35°C ; 5% to 80% relative humidity

Power - 100-240 Volt AC, (50-60 Hz).

### Operational Features:

Able to perform tests to specifications as defined by CLIA and CLSI standards including satisfactory CAP peer group comparison. All required tests must be FDA approved.

Freezing point depression methodology

Ability to perform fully automated muliti-sample testing in < 3 minutes

Small sample volume, 100 microliters.

Primary tube sampling capabilities in order to reduce variations in pipetting.

Minimal recurring preventative maintenance and time spent on routine maintenance (daily, weekly, monthly, etc).

Ease of operation with state of the art technology.

Calibrators must be traceable to a recognized national standards organization as stated by the Clinical and Laboratory Standards Institute (CLSI) and/or College of American Pathologists (CAP).

A Quality Control software package with the capability to produce Levy-Jennings graphs and perform system linearity checks will meet the requirements of the laboratory's regulatory agency.

To meet patient safety standards, the osmometer must also have a barcode scanner for positive patient identification.