



# Design Qualification (DQ) Vision<sup>®</sup> Microette<sup>™</sup> Autosampler

## Purpose

The purpose of this document is to provide information for the end user to define the functional and operational specifications of the instrument and criteria for selection of the vendor based on the intended purpose of the instrument; as per USP chapter <1058>.

## Product Design

Hanson Research is a certified ISO 9001:2008 corporation.

All Hanson Research products follow a documented development cycle as per Quality Management Work Instruction QW7.02.

This process includes the development and maintenance of a design history file which includes, but is not limited to:

- Marketing Requirements
- Functional Specifications
- Schedule
- Design
- Design Reviews
- Design Changes
- Design Verification
- Design Validation
- Production Plan

The design history files for products is maintained for the life of the product and at least 5 years after production of the product has ended before archiving.

These documents may be audited upon customer request.

## Product Conformance

Hanson Research certifies that the Vision Microette autosampler, including hardware and firmware, was designed, evaluated, validated, inspected, and tested to approved specified quality requirements of Hanson Research Corp. in accordance with the following specifications:

- Current USP <1724>



## Design Qualification (DQ) Vision<sup>®</sup> Microette<sup>™</sup> Autosampler

### Vision Microette Features

- ✓ Precision syringe pump autosampling system
- ✓ All-inert 2.5 mL syringes, valves, tubing and fluidics
- ✓ Choice of Single-Group (1 diffusion cell group) or Multi-Group (up to 3 groups)
- ✓ Volume accuracy and repeatability  $\pm 1\%$
- ✓ Handles problem drugs, surfactants and buffers
- ✓ Trouble-free maintenance, no peri-pumps or check valves
- ✓ Full color touchscreen with intuitive menus and programming
- ✓ Up to 100 protocols (create, manage and save routines)
- ✓ Upload & download programs with flash drive
- ✓ Electronics and firmware include 32-bit digital technology
- ✓ Print to both serial and PostScript-capable network printers
- ✓ Alarms for sampling, maintenance and calibration
- ✓ Supports 21 CFR Part 11 compliance
- ✓ USP, FDA, ASTM, EP, and JP compliant
- ✓ Precision Z-Y diffusion test sample collector
- ✓ AutoFill features seamless integration with Vision Microette
- ✓ Choice of easy install collection racks with rack detection
- ✓ Collect in test tubes for UV or vials for HPLC & UPLC analysis
- ✓ CE, CSA, and RoHS compliant; includes earth-friendly packaging

### Vision Microette Specifications

**Weight:** (dry) 21.3 kg (47.0 lbs.)

**Size:**

Height: 46.8 cm (18.4 in.)

Width: 38.1 cm (15.0 in.)

Depth: 66.0 cm (26.0 in.)

**Power** (external power supply):

Input: 100-240 V~, 50-60 Hz, 1.5 A max

Output: 24 VDC, 3.75 A, 90 W

### AutoFill Specifications

**Weight:** (dry) 14.5 kg (32.0 lbs.)

**Size:**

Height: 40.1 cm (15.8 in.)

Width: 28.0 cm (11.0 in.)

Depth: 47.3 cm (18.6 in.)

**Power** (external power supply):

Input: 100-240 V~, 50-60 Hz, 1.5 A max

Output: 24 VDC, 3.75 A, 90 W



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### Drive Stand with Stirring Drive and Control Specifications

**Size:**

Width: 25 cm (10 in.)

Depth: 61 cm (24 in.)

Height: 20 cm (8 in.)

Weight: 11.8 kg (26.0 lbs)

**Power (2mag MIXcontrol):**

Voltage: 100-240 VAC

Frequency: 50/60 Hz

Power Dissipation: 0.8 A (96 Watts)

Phase: Single

### Circulating Waterbath Specifications (PolyScience AP007H200)

**Size:**

Width: 23 cm (9 in.)

Depth: 51 cm (20 in.)

Height: 44 cm (17 in.)

**Power:**Voltage: 120 VAC or 230 VAC  $\pm$  10% Grounded

Frequency: 50/60 Hz

Power Dissipation: 8.8 A ( 1012 Watts)

Phase: Single

**NOTE:** *The above specifications for non-Hanson products are for reference only. Review the individual operation manuals for exact specifications.*

### General Specifications

**Sampler Volume Accuracy:**0.5 to 2.5 mL:  $\pm$  0.025 mL2.5 to 5.0 mL:  $\pm$  0.050 mL5.1 to 7.5 mL:  $\pm$  0.075 mL**Sampling:**

Minimum sample interval: 1 min (5 min is normal)

Maximum sample interval: 998 hours, 59 min (998:59)

Sample time points: 50 max

Maximum sample volume: 90% of vial capacity

**Collection:**

13 x 100 rack: 18 x 8 test tubes, 144 total

16 x 100 rack: 18 x 8 test tubes, 144 total

12 x 32 rack: 21 x 8 vials, 168 total

UPLC rack (12 x 32): 3 trays 6 x 8 vials, 144 total

**Septum:** Pre-cut type only

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## Wetted Materials

	Material	304 Stainless Steel	Borosilicate Glass	CPVC (Chlorinated polyvinylchloride)	EPDM (Ethylene Propylene )	PCTFE (Chlorotrifluoroethylene)	PEEK (Polyether ether ketone)	ETFE (Ethylene tetrafluoroethylene)	PTFE (Polytetrafluoroethylene)	FKM/FPM (Fluoroelastomers)	PVDF (Polyvinylidene fluoride)	Tygon	SAN (Styrene/Acrylic/Nitrile)	Ethylene Propylene Elastomers
<b>Vision Microette Multi-Group</b>					X		X	X	X		X			X
<b>Vision Microette Single-Group</b>		X			X		X	X	X		X			X
Syringe 2.5 mL			X			X			X					
<b>AutoFill</b>							X	X	X		X	X	X	
<b>Cells and Tops</b>			X						X					
Helix		X												
<b>Service Kit</b>														
Tubing		X										X	X	
Flask													X	
Flask cover									X					



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### Vision Microette Warranty

Hanson Research (Hanson) products are warranted for one full year including parts and labor. Service contracts and Preventive Maintenance contracts are available for post-warranty support. International dealer warranties may vary. Hanson makes no warranty, expressed or implied, for glassware, consumables, or products not manufactured by Hanson, as evidenced by nameplate on the item or other designation. Hanson will give responsible assistance to buyer in obtaining from the respective manufacturer whatever adjustment is reasonable in light of manufacturer's own warranty. Hanson shall be released from any and all obligations under any warranty, either expressed or implied, if the product covered is repaired or modified by other than its own personnel, or made without written authorization from Hanson. There are no other warranties, expressed or implied, and Hanson shall not be liable under any circumstances for consequential damages.