



Design Qualification (DQ)

Vision® G2 AutoPlus™ 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 AutoPlus 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 <711>
- EP (2.9.3)
- JP (6.10)



Design Qualification (DQ) Vision® G2 AutoPlus™ Autosampler

Vision G2 AutoPlus Features

- ✓ Precision syringe pump autosampling system
- ✓ All-inert 5 mL syringes, valves, tubing and fluidics
- ✓ Choice of DissoScan (1 tester) or Maximizer (multiple testers)
- ✓ Choice of 6 or 8 sampling syringes (for 6 or 8 vessels)
- ✓ Volume accuracy and repeatability $\pm 1\%$
- ✓ Seamless integration with G2 Classic 6, Elite 8, and AutoFilter
- ✓ Automatic media replace standard with Maximizer
- ✓ Convenient "Auto-Start" feature
- ✓ Sample dilutions with AutoFill collector
- ✓ In-line filter block kit (easy tubing and filter connections)
- ✓ Handles problem drugs, surfactants and buffers
- ✓ Trouble-free maintenance, no peri-pumps or check valves
- ✓ Full color touch screen 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
- ✓ ISO 9001 quality certified
- ✓ Supports 21 CFR Part 11 compliance
- ✓ USP / FDA / ASTM / EP / JP compliant
- ✓ Precision X-Y dissolution test sample collector
- ✓ AutoFill features seamless integration with Vision AutoPlus
- ✓ Choice of easy install collection racks with rack detection
- ✓ Collect in test tubes for UV or vials for HPLC & UPLC
- ✓ New wash port with end of test wash routine
- ✓ Sample retrieval return to vessel accessory
- ✓ AutoFill is designed and manufactured with CETAC Technologies USA
- ✓ CE / CSA / RoHS compliant, includes earth-friendly packing

Vision G2 AutoPlus 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



Design Qualification (DQ) Vision[®] G2 AutoPlus[™] Autosampler

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

General Specifications

Sampler Volume Accuracy:

0.5 to 5.0 mL: ± 0.05

5.1 to 10.0 mL: ± 0.10

10.1 to 15.0 mL: ± 0.15

Sampling:

Minimum sample interval: 1 sec (5 minutes between sample points recommended for pumping)

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

Vision G2 AutoPlus		
Part Number	Description	Wetted Materials
	Tubing	PTFE, ETFE
91-450-056	DissoScan Valve	PEEK, EPDM, 304 SS
91-450-076	Maximizer Valve	PEEK, EPDM, PFE, 304 SS
60-200-550	5 mL Syringe	PTFE, PEEK, Borosilicate Glass

AutoFill		
Part Number	Description	Wetted Materials
61-207-717	Home Port Stand	PVDF
61-207-723	PEEK Needles	PEEK
91-030-051	16 mm x 100 mm Test Tube	Borosilicate Glass
91-030-150	12 mm x 32 mm Vials	Borosilicate Glass, Silicone, PTFE
61-107-003	16 mm Evaporation Caps	Polyethylene
61-105-007	Retrieval Block	PVDF
61-105-029	Syringe Barrel	Borosilicate Glass
91-425-028	Viton O-Ring	Viton
91-951-004	Silicone Compound	Silicone

Vision G2 AutoPlus 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.