



# Design Qualification (DQ) Vision® G2 Elite 8™ Dissolution Tester

## 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 Elite 8 dissolution tester, 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)
- ASTM E2503-13



## Design Qualification (DQ) Vision® G2 Elite 8™ Dissolution Tester

### Vision G2 Elite 8 Features

- ✓ Easi-Lift™ moveable drive head with multi-lock positions
- ✓ 8 Precision drive spindles with spindle shafts (use 6, 7, or 8)
- ✓ 8-Position Easi-Lock™ vessel plate (use 6, 7, or 8 vessels)
- ✓ Standard footprint (4 across & 2 deep)
- ✓ Automation-ready (with optional AutoMag™ & SuperMag™)
- ✓ Precision control for speed 25-250 rpm, temperature 25-55 °C
- ✓ Elegant, ergonomic design with workhorse performance
- ✓ Highest quality components and engineering
- ✓ Minimal user adjustments for easy set up and go
- ✓ Independent Vision Heater system
- ✓ Rugged molded waterbath with fast heat-up & low level drain
- ✓ Digital temperature probe (1) for use in bath and vessels
- ✓ 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 network printers
- ✓ Alarms for sampling, maintenance and calibration
- ✓ ISO 9001 quality certified
- ✓ Security system supports 21 CFR Part 11 compliance
- ✓ USP/FDA/ASTM/EP/JP compliant
- ✓ CE/CSA/RoHS compliant, includes earth-friendly packing



# Design Qualification (DQ) Vision<sup>®</sup> G2 Elite 8<sup>™</sup> Dissolution Tester

## Vision G2 Elite 8 Specifications

### **Weight:**

Main unit, dry: 63.5 kg (140 lbs.)  
Main unit, bath and  
vessels filled with water: 90.8 kg (200 lbs.)

### **Size:**

Height: 87.6 cm (34.5 in.)  
Width: 67.3 cm (26.5 in.)  
Depth: 58.5 cm (23.0 in.)

### **Bath Capacity:**

With 8 vessels: 19 liters (5 gallons)

### **Power** (external power supply):

Input: 100-240 V~, 50-60 Hz, 1.5 A max  
Output: 24 VDC, 3.75 A, 90 W

### **Spindle Speed:**

Range: 25 to 250 rpm  
Accuracy:  $\pm 1$  rpm  
Displayed Resolution: 0.1 rpm

### **Temperature:**

Programmable Temperature Range: 25.0 to 55.0 °C  
Accuracy:  $\pm 0.5$  °C  
Control:  $\pm 0.1$  °C

### **Digital Temperature Probes (all probes):**

Range: 10 to 60 °C  
Accuracy:  $\pm 0.1$  °C from 30 - 55 °C  
Displayed Resolution: 0.01 °C  
Minimum Submersion Depth: 25 mm  
Response Time: < 45 seconds (normally 30 sec.)

## Vision G2 Heater

**Weight:** 4.1 kg (9 lbs.)

### **Size:**

Height: 22.9 cm (9.0 in.)  
Width: 24.1 cm (9.5 in.)  
Depth: 16.5 cm (6.5 in.)  
Power Input: 100 - 230 V  $\pm 10\%$ , 50-60 Hz  
Power: 700-1200 W

# Design Qualification (DQ)

## Vision® G2 Elite 8™ Dissolution Tester

### Wetted Materials

Material	#19 Amber Stain	316 Stainless Steel	Borosilicate Glass	CPVC (Chlorinated polyvinyl chloride)	PVDF (Polyvinylidene fluoride)	PEEK (Polyether ether ketone)	PE (Polyethylene)	PVC (Polyvinyl chloride)	Silicone	ETFE (Ethylene tetrafluoroethylene)	PTFE (Polytetrafluoroethylene)	Polypropylene
<b>Apparatus</b>												
Spin-Basket Shaft, USP, 316 SS		X										
Spin-Paddle, USP, PVDF					X							
Basket, 316 SS		X										
<b>Vessels</b>												
Vessel, Easi-Lock, USP, Precision, 1 L, Glass			X	X								
Vessel, Easi-Lock, USP, Precision, 1 L, Glass, Amber	X			X								
<b>Probes</b>												
Manual Sampling Cannula (PEEK)						X						
Manual Sampling Cannula (316 SS)		X										
Auto-Probe, 1/8 in. (PEEK)						X						
Auto-Probe, 1/16 in. (316 SS)		X										
Probe, Sample, Fixed Vessel-Mount		X										
Digital Temperature Probe		X										
<b>Vessel Covers</b>												
Vessel Cover, Easi-Lock				X				X				
Vessel Cover, Easi-Lock, G2								X				
Vessel Cover, ADD (Auto-Dosage Delivery)				X				X	X			
<b>Filters</b>												
Filter, Sample, 10 micron, 1/8 in.							X					
Filter, Sample, 10 micron, 1/8 in., PVDF (100/pk)					X							
Cartridge Filters (for Vision Vessel Mount Probes)							X					
<b>Assemblies &amp; Miscellaneous</b>												
Tubing Harness					X					X	X	
AutoMag					X	X				X	X	
Disposable syringe 10 mL		X							X			X



## Design Qualification (DQ) Vision<sup>®</sup> G2 Elite 8<sup>™</sup> Dissolution Tester

### Vision G2 Elite 8 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.