

# Design Qualification (DQ) Vision<sup>®</sup> AutoFilter<sup>™</sup> Changer



## 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 AutoFilter changer, including hardware and firmware, was designed, evaluated, validated, inspected, and tested to approved specified quality requirements of Hanson Research Corp.

# Design Qualification (DQ) Vision® AutoFilter™ Changer



## Vision AutoFilter Features

- ✓ Automatically installs new filters into the sample path
- ✓ Supports many standard 25 mm in-line filters and automation compatible filters
- ✓ Catch bin allows for easy disposal of used filters
- ✓ Compact design requires little bench space
- ✓ Seamless integration with Vision AutoPlus
- ✓ Stand-alone operation that can be used with any dissolution tester and autosampler
- ✓ No filter present or upside down filter detection for each slot
- ✓ Configurable for 6, 7, or 8 filter positions
- ✓ Handles problem drugs, surfactants and buffers
- ✓ Trouble-free maintenance
- ✓ Reliable rotary separation mechanism
- ✓ Jam and misfeed detection
- ✓ 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
- ✓ ISO 9001 quality certified
- ✓ Supports 21 CFR Part 11 compliance
- ✓ USP/FDA/ASTM/EP/JP compliant
- ✓ CE/CSA/RoHS compliant, includes earth-friendly packing

## Vision AutoFilter Specifications

**Weight:** (dry)            28.6 kg (63.0 lbs.)

**Size:**

Height (with 10 in. filter tubes):    54.6 cm (21.5 in.)

Width:                                        48.9 cm (19.25 in.)

Depth:                                        43.2 cm (17.0 in.)

**Power** (external power supply):

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

Output:                 24 VDC, 3.75 A, 90 W

**Other:**

Time to change filters (minimum):    35 seconds

Filter Capacity:                            18 – 25

Sample time points:                        50 max

**Filters:**

Maximum Filter Height:                 2.29 cm (0.90 in.)

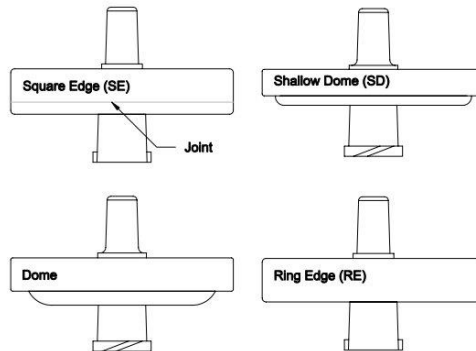
Maximum Filter Body Diameter:        3.02 cm (1.19 in.)

Maximum Filter Body Thickness:        0.66 cm (0.26 in.)

# Design Qualification (DQ) Vision<sup>®</sup> AutoFilter<sup>™</sup> Changer



Compatible Filter Styles:



## Wetted Materials

ETFE (Ethylene tetrafluoroethylene), PTFE (Polytetrafluoroethylene)

## Vision AutoFilter Warranty

Hanson Research (Hanson) products are warranted for one full year including parts and labor. Service contracts and Preventive Maintenance (PM) 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.