

Considerations for Use of the Viresolve® Pro Micro 40 Scaling Tool

The Viresolve® Pro Micro 40 Device is a small-scale tool, designed for virus filtration process development and viral clearance evaluations. This redesigned small-scale tool provides the same robust parvovirus retention as our larger scale Modus and Magnus Devices. The Micro 40 Device kit, Catalogue Number VPMKVALNB9, replaces the Micro Device kit, Catalogue Number VPMNVALNB9. Each Micro 40 Device kit contains 9 devices, 3 devices from each of 3 device lots, and is designed for process development, optimization and viral clearance studies.



Figure 1. A: Viresolve® Pro Micro Device, B: Viresolve® Pro Micro 40 Device.

Similarities and Differences: Micro vs Micro 40 Devices

The Micro 40 Devices contain the same two layers of Viresolve® Pro virus retentive membrane as the Micro Devices and end-users can expect the same throughput and virus retention performance. Table 1 summarizes similarities and differences between the Micro and Micro 40 Devices.

Table 1: Comparison between Micro and Micro 40 Devices

	Parameter	Micro Device (VPMNVALNB9)	Micro 40 Device (VPMKVALNB9)
Similarities	Number of membrane layers	2	2
	Membrane used	Polyethersulfone (PES)	PES
	PhiX-174 Retention	≥4.0 log	≥4.0 log
	Shelf Life	3 years	3 years
	Sanitization	Dynamic flush: 0.5 N/1 hr/25 °C Static soak: 0.5 N/16 hr/25 °C	Dynamic flush: 0.5 N/1 hr/25 °C Static soak: 0.5 N/16 hr/25 °C
Differences	Housing Materials of Construction	Polypropylene/Polyethylene (copolymer)	Polyvinylidene fluoride (PVDF)
	Bonding technology	Crimp seal	Thermal bonding
	Forward Pressure Rating	50 psig (4–30 °C)	60 psig (4–30 °C)
	Effective Filtration Area	3.1 cm ²	3.4 cm ²

The upgrade in device format results in benefits to the end-user, outlined in Table 2.

Table 2: Benefits of upgrade for the end-user

Parameter	Benefit
Housing Materials of Construction	PVDF housing materials are aligned with those of Modus and Magnus Devices and enable extractable and leachable (E&L) studies at small scale.
Bonding technology	Thermal bonding technology in the Micro 40 Devices now matches that of larger device scales, improving robustness of virus retention under elevated pressure conditions.
Forward Pressure Rating	Thermal bonding resulted in an increase to forward pressure specification enabling end-users to realize the benefits of higher flux and faster processing time.

Throughput and Flux Performance with Micro 40 Devices

The effective filtration area of the Micro 40 Device is 3.4 cm² corresponding to an increase of ~10% as compared to the Micro Device with an area of 3.1 cm². As the filter membrane has not changed, end-users should expect the same volumetric throughput or filter capacity from the Micro 40 Devices when normalized for filtration area. Figure 2 shows the similarity in throughput and flux performance from Viresolve[®] Pro Micro and Micro 40 Devices with a human IgG fluid stream.

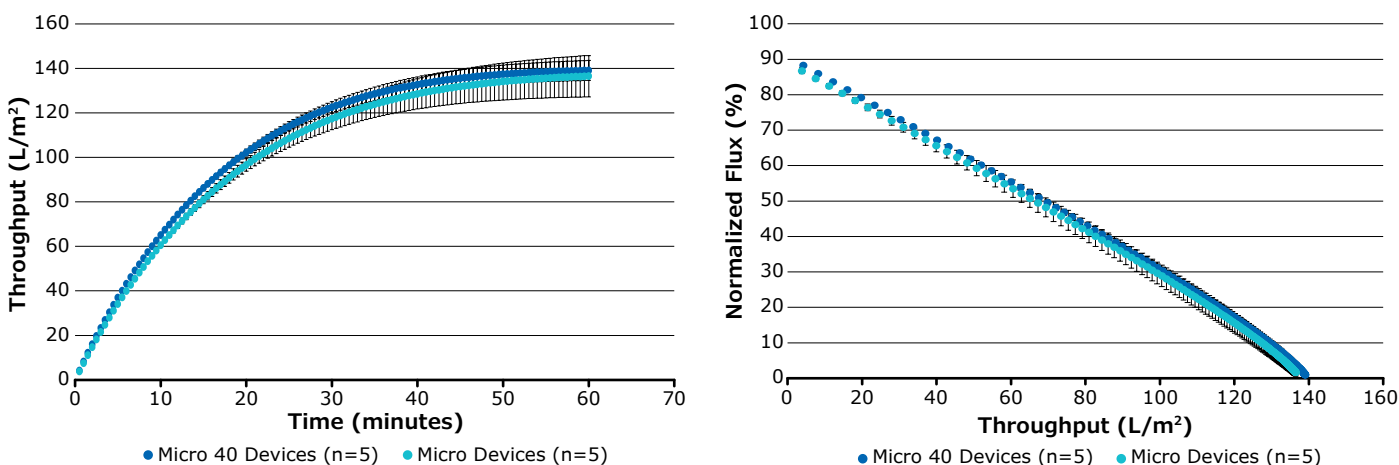


Figure 2. Throughput and normalized flux of Viresolve[®] Pro Micro and Micro 40 Devices in an IgG fluid stream. Flux was normalized to buffer flux at 30 psi.

When coupled with the Viresolve[®] Pro Shield or Viresolve[®] Pro Shield H prefilters, the increased filtration area of the Viresolve[®] Pro Micro 40 means there is no longer a 1:1 ratio between prefilter and virus filter in small-scale studies. Filter throughput is estimated during small-scale process development studies to determine throughput targets for viral clearance evaluations. Filter throughput achieved during viral clearance evaluations is then used to establish filtration area requirements for the process. In small-scale process development and clearance studies, the lower prefilter to Viresolve[®] Pro Device filtration area ratio results in the prefilter being undersized and adds an additional safety factor for consideration in calculations of filtration area requirements.

Virus Retention with Micro 40 Devices

As the filter membrane is the same, the change in device format does not impact the virus retention performance. Figure 3 shows virus retention from filtrate pool samples collected from Viresolve[®] Pro Micro and Micro 40 Devices challenged with PhiX-174 in an IgG solution.

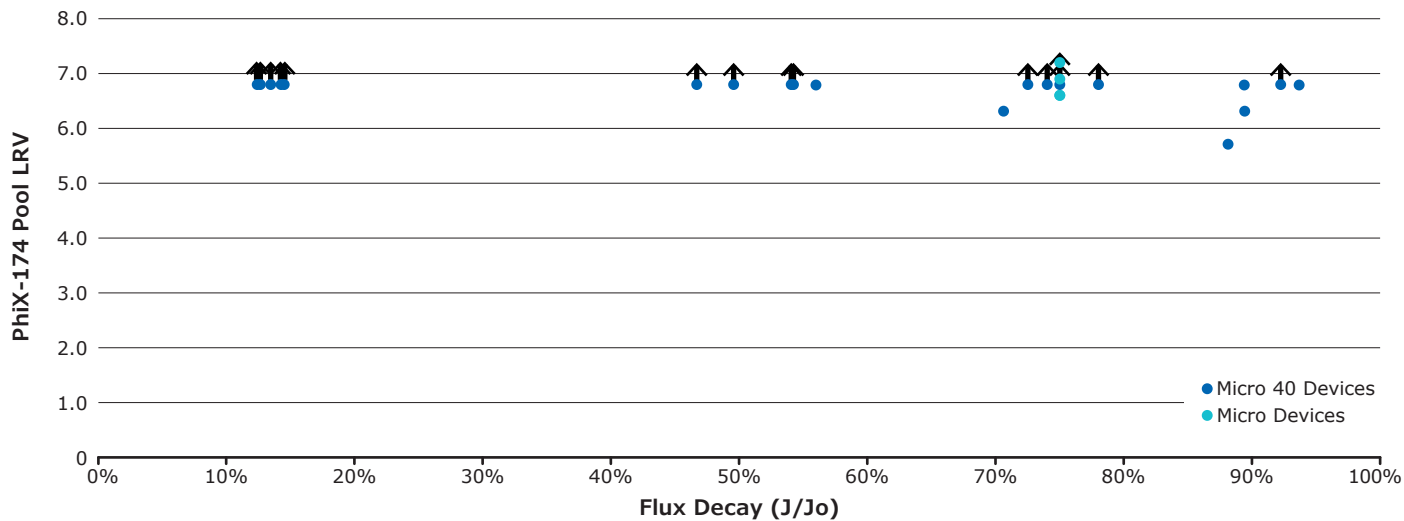


Figure 3. PhiX-174 retention in Viresolve® Pro Micro and Micro 40 devices.

Summary

Our experience manufacturing the Viresolve® Pro Solution enabled us to make improvements in the small-scale device manufacturing process. These improvements resulted in the Micro 40 Device which is more representative of process-scale devices while providing the same reliable throughput and viral retention performance. Key benefits include:

- The materials of construction and bonding technology of small-scale devices now match the larger scale devices.
- E&L studies can be performed on the small-scale device.
- Forward pressure specification of the Micro 40 Devices has been increased to 60 psig, enabling validation of processes that require higher flux and lower processing times.

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

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