

# Processing Economics of the Millipore Pod System Versus Millistak+<sup>®</sup> HC Lenticular Stacks

## Introduction

Charged depth filters have been employed in biotech upstream clarification processes for decades. The particle capture mechanisms at work in charged depth filters are sieving, entrapment and adsorption, making them unique when compared to traditional membrane prefilters. Millipore improved the effectiveness of charged depth filters by introducing the multi layer Millistak+ HC media to the marketplace. The multi layer format requires fewer housings and compresses a multiple stage filtration process into a single step. The net effect for the end user is process compression, labor time savings, and ease of use.



Millipore now offers the Millistak+ HC charged depth filter media in a disposable format called the Pod. The Pod platform is a self-contained device that requires no housings. Because there are no large housings, the system volume of the Pod is approximately 20% less than the traditional lenticular stack format. With the Pod platform it is possible to have no product contact with the associated hardware, eliminating the need for clean in place (CIP) and the associated validation.

This document presents an economic analysis that compares the Pod platform to lenticular stacks. The analysis is based on filter cost, usage of process fluids, and labor. Not included in the calculations are intangible aspects that are essential to technology selection (discussed on the following pages).

## Assumptions

Table 1 presents the baseline assumptions for process fluids and labor. Two scenarios are shown, based on two costs per liter of water for injection (WFI). The cost per liter is based on process fluids produced in volumes >1000 liters and in house.

The process steps considered in the analysis are:

- Loading the filters
- Venting the system
- Wetting
- Buffer conditioning
- Buffer recovery and blow down
- Unloading the filters
- CIP (for lenticular stacks only)

Process considerations not in the calculations include:

- Increased product yield due to lower hold up volumes
- Product safety (lot-to-lot carry over)
- Cost of CIP validation (estimated \$20,000 year)
- Operator safety (hoisting large housing bells, operator exposure)
- Ease of use
- Speed to market
- Hardware flexibility (Pod system can run 5.5 to 33 m<sup>2</sup>)

## Analysis

Contributing factors to the differences in operating cost for the Pod system versus the lenticular stacks include: filter cost, labor, CIP operation, and upstream volume difference.

Figures 1 and 2 present the cost calculations for scenarios 1 and 2 listed in Table 1 above.

For the two WFI cost scenarios, the analysis shows that when some very basic process costs are taken into account the operating cost of using the Pod system ranges from 0.9 to 1.2 times the operating cost of using traditional lenticular stacks. As the price of WFI increases past \$1.30 per liter, the operating cost of running the Pod system is less than that of a lenticular stack system.

It shows also that the major contributing operating costs per run are WFI usage and CIP solution usage. Since the Pod system requires no CIP, the CIP solution and rinse WFI usage is zero.



**Table 1. Raw Materials Cost**

	Scenario 1 (\$L)	Scenario 2 (\$L)
WFI	0.5	2.0
Buffer	1.0	2.5
CIP Solution	1.0	2.5
Labor Cost = \$75/hr/person		

**Table 2. CIP and Passivation Assumptions**

	Flow per Housing (L/min)	Duration (min)	Number of Bursts	CIP Volume (L)
CIP/Passivation Fluid	83	2	3	500
CIP Rinse WFI	83	1	3	250

**Table 3. System Specifications**

	Area (m <sup>2</sup> )	Upstream Volume (L)
3 Rack Pod System	29	154
2 Process Scale Millistak+ HC Housings	29	194
Batch Size = 6,000 Liters		

Figure 1. Cost Comparison for WFI = \$0.5 per Liter\*

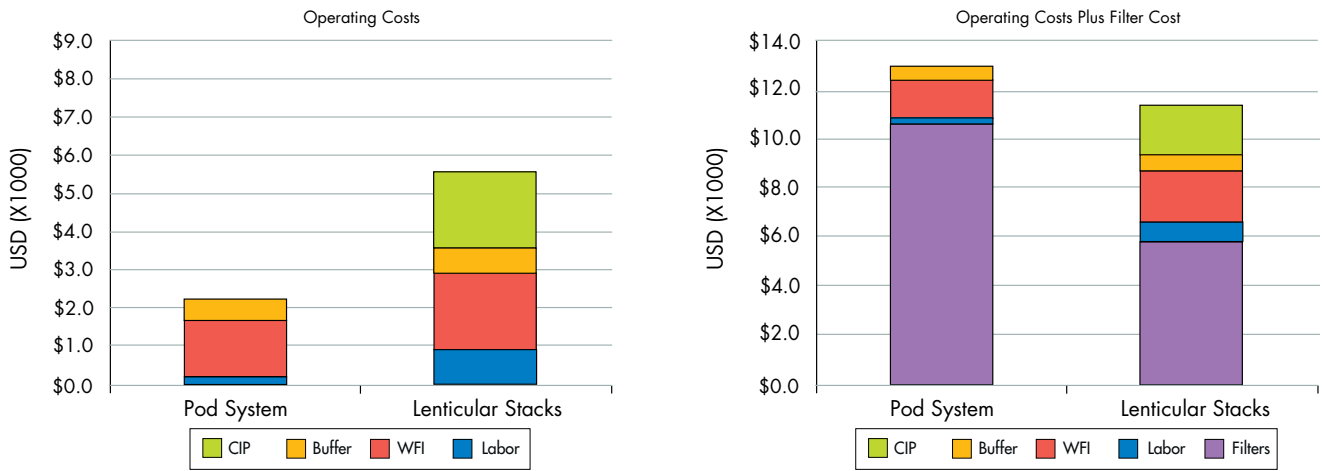
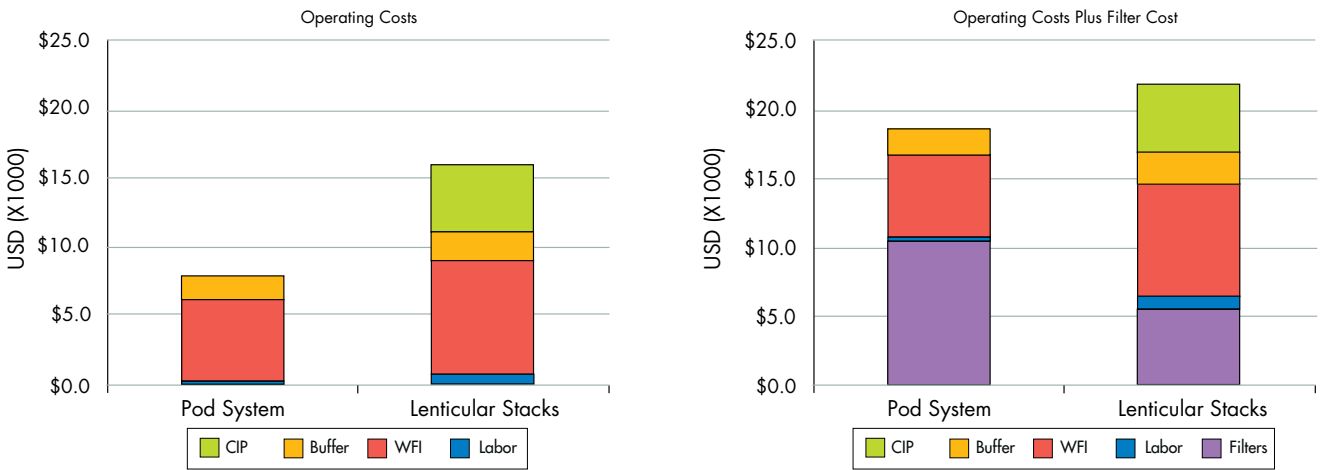


Figure 2. Cost Comparison for WFI = \$2 per Liter\*



\*All values in US dollars

## Conclusions

The analysis indicates that making a comparison based only on normalized filter cost (\$/m<sup>2</sup> filter area) does not capture the actual cost of employing either technology in a process.

Additionally, from a commercial manufacturing standpoint a main driver for technology selection is often the intangible aspects of using the selected technology. The cost of one lost batch per year

(because of cross contamination for example) could be >\$12 million (in this case study: 6000 liters, 1g/liter, \$2000/g), making the cost of employing the Pod or lenticular stacks a minor consideration when selecting either technology.

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Lit. No. TB1076EN00 Rev. - Printed in U.S.A. 07/07 07-310

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