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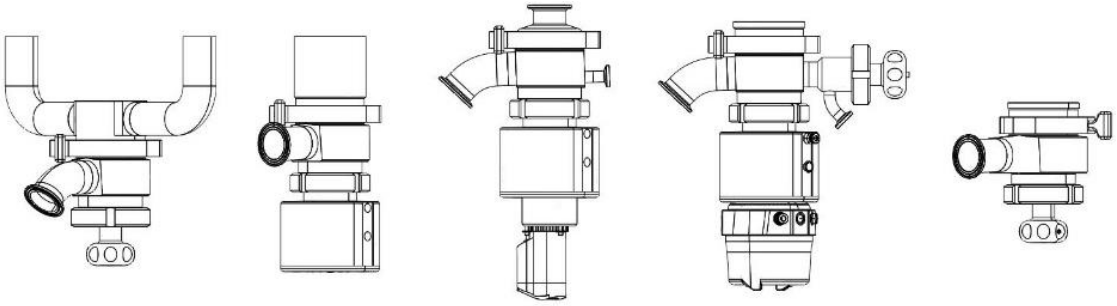
Cleanability and Drainability Performance of PBM Igenix® Radial Diaphragm Valves (Silicone)



PBM's Igenix® Radial Diaphragm Valves (RDV) with their ability to self-drain similar to or better than *ASME BPE-2016* requirements (a pipe inclined at ¼" per foot) and to be cleanable – can enhance the safety and effectiveness of critical bioprocess applications. In bioprocessing, the assumption is that all valves are drainable and cleanable without hold-up, which is not always the case. We at PBM have performed extensive development work to ensure these issues are addressed. Compared to its competition, PBM's RDV is as cleanable and is more drainable as validated by a recognized third party testing authority.

An often overlooked but critical component in bioprocessing systems, the RDV is one type of diaphragm valve typically used as a tank bottom outlet valve. The market for the tank bottom valve evolved from the ball valve, which was primarily used in the cosmetics and food industries. Over fifty years from the early 1960s, PBM has developed and refined its radial tank outlet valve to what it is today. A traditional tank bottom ball valve, shown in **Figure 1**, relies on upstream pressure to seat the ball against the downstream set, is not ideal in low pressure applications, and adds 'dead space' in tank bottom applications. Versus the traditional tank bottom ball valve, the RDV avoids dead space and is also easy to clean manually by dismantling.

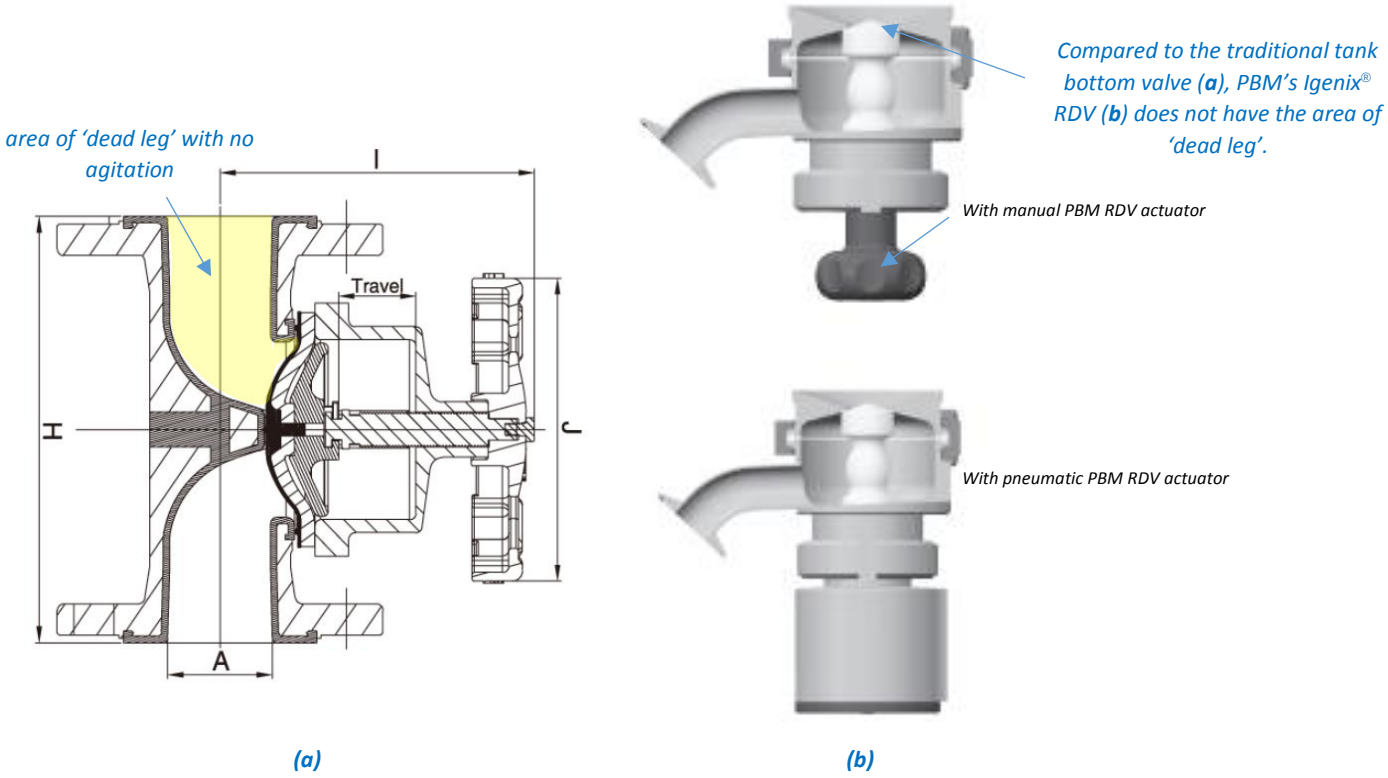
Building upon our 50 years of experience in the valve industry, PBM has recognized that the bottom outlet valve has Cleanability and Drainability issues.

What follows is the data to show how PBM's Igenix® RDV is different from the competition.

Section SG-2.3.1.2 (Sealing Components) of the ASME BioProcessing Equipment (BPE) Standard (*ASME BPE-2016*) describes the types of diaphragm valves as weir diaphragm valve/weir diaphragm tank bottom valve, radial diaphragm valve/radial diaphragm tank bottom valve, weirless diaphragm valve, linear control valve, and regulator valve. All of these diaphragm valves have a dynamic seal that shuts off or controls flow through the valve (at the seat) and a static seal at the shoulder that prevents process fluids from escaping into the atmosphere (non-process area). These two seals are combined in the diaphragm and both must be maintained to ensure that the valve remains cleanable and sterile; if either the dynamic (seat) seal or the static (shoulder) seal fails, contamination of the bioprocess could occur. The USP Class VI-approved Silicone diaphragm is the wear part of the RDV, as it is exposed to mechanical stress throughout its service life and therefore is the component replaced as necessary at maintenance intervals.

Figure 1 (Comparison between Traditional Tank Bottom Valve vs. PBM Radial Diaphragm Valve)
Image (a) referenced from

http://www.buenoeco.com/userfiles/PFA%20Lined%20Diaphragm%20Valve%20PD-51-d.jpg.



Manual and pneumatic PBM Igenix® (white and clear silicone) Radial Diaphragm Valves (RDV) were evaluated under simulated process conditions for cleanability and drainability. Inspection and evaluation of the flow path were performed after hold-up testing to assess the extent to which the Radial Diaphragm Valves in sizes 1", 1½", 2", and 3" were self-draining with respect to *ASME BPE-2016* Part SD (Systems Design). As a participating member of the BPE Standards Committee, we at PBM know the rules of the game and meet or exceed them. Overall:

- Cleanability testing has concluded that a typical, routine cleaning cycle should effectively clean all sizes of the PBM Igenix® RDV (silicone) (Table 1). A minimum cleaning cycle is warm (65°C) water at turbulent flowrates (5 feet/second) with up to 12 valve actuations over eight minutes sizes.

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  A typical cleaning cycle, such as *ASME BPE-2016's* CIP cycle, cleaned one of the sizes (1-1/2") in full and is expected to clean all sizes of the valve.

- **Drainability testing** has concluded that the PBM Igenix® RDV (silicone) is the *same or more drainable* than a pipe inclined at ¼" per 12" (1.2°) (based on *ASME BPE-2016)* in sizes ½" through 3". Testing showed that PBM's 1½" RDV is four times more drainable than a competitor's RDV; it also demonstrated a minimal variance in drainability across the RDV sizes versus that of the pipe which was shown to have more significant variance by size.

Cleanability

With a properly developed cleaning cycle of these rinse parameters, soil will be effectively removed from the wetted space of all PBM Igenix® RDVs.
A stronger cleaning cycle, such as that of *ASME BPE-2016's* CIP cycle with elevated pressure (65-80 psig), more time (30 minutes), more actuations (105), higher temperature (75-85°C), and the presence of a chemical media (0.5 N NaOH), will effectively remove soil from the wetted space of the RDV.
Changes in design of PBM's Igenix® Radial Diaphragm Valve over the course of testing have improved its cleanability and drainability.
A Cleanability test on the 1½" Igenix® RDV, based on abbreviated CIP exposure test conditions from *ASME BPE-2016's* Appendix J-1.2.2, showed that elevated pressure (65-80 psig), more time (40 minutes), more actuations (60), higher temperature (75-85°C), and the presence of a chemical media (0.5 N NaOH) facilitated complete soil removal. If the processor chooses to use the *ASME BPE* CIP cycle, PBM's Igenix® RDV will be effectively cleaned.

Table 1 (Cleanability of PBM Igenix® RDVs)

A (Acceptable, Grade 3) – no further action necessary

Cleanability by Location	1"	1-1/2"	1-1/2"	2"	3"
Basin	A/3	A/3	A/3	A/3	A/3
Diaphragm	A/3	A/3	A/3	A/3	A/3
Gasketed Lid Interface	A/3	A/3	A/3	A/3	A/3
Outlet Port	A/3	A/3	A/3	A/3	A/3

1-1/2" – BPE CIP

Entrapment Risk in RDVs

The entrapment risk of these radial diaphragm valves is very different from other bioprocess components. Overall, cleaning is very process-specific; it is dependent upon each process application and each will require proper qualification and testing. Every soil is different and, if entrapped, the cleaning needs to be able to get it out. There may be a 'perfect storm' of exceptionally bad soil that is allowed to dry and is not cleanable with a reasonable cycle.
Many other process components and configurations can be easily cleaned using BPE's nominal cleaning rates of 5 feet/second *without* actuation. Cleaning in bioprocessing operations does not routinely involve cycling the valve. 'Systems or equipment that cannot be gravity-drained shall utilize forced expulsion with pressurized gas where line drainability is required,' as per *ASME BPE-2016* Section SD-2.4.3.4(b).

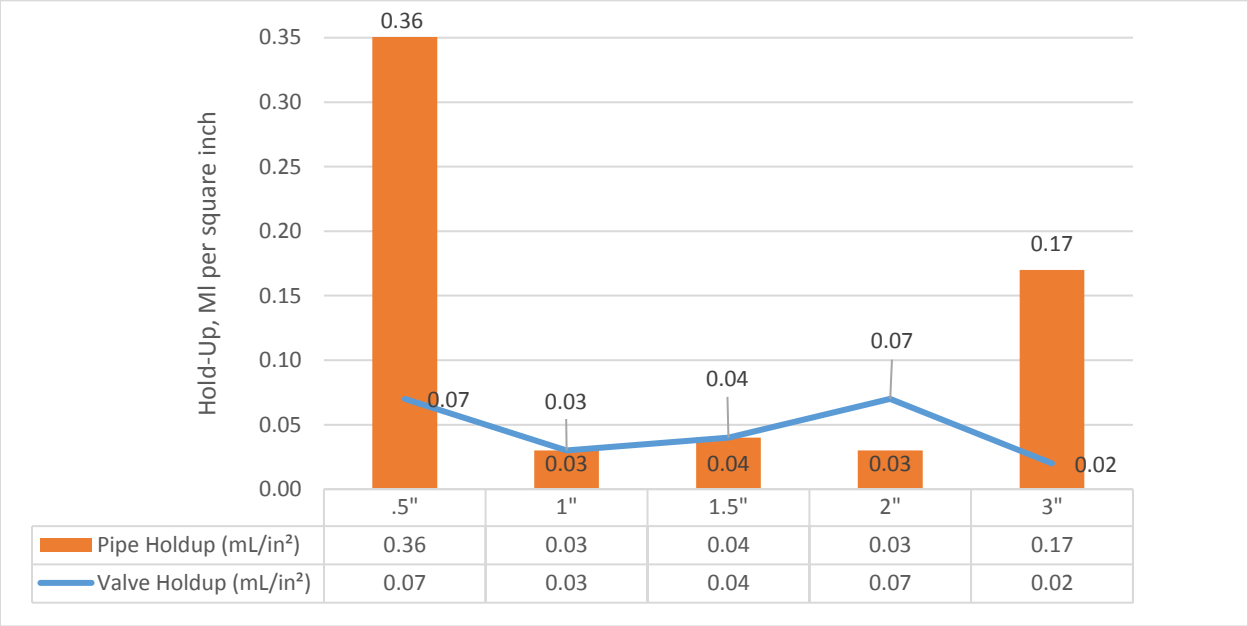
The radial diaphragm valve represents one of these instances; actuation should be employed to help clean the valve, due to the inherent valve design geometry with the wide valve chamber that contains a diaphragm with its contoured, folded design.
The drivers for successful cleanability include: contact between cleaning solution and component (considering its design), diffusion (including temperature and chemistry), and time. Due to the inherent radial diaphragm valve design, PBM paid close attention to areas within the RDV that by design, were hard to clean.

- Media can be retained within the folds and curvature of the contours of the silicone **diaphragm**; actuation of the valve was shown to help release the entrapped soil from the diaphragm.
- Valve actuation causes the valve's diaphragm to elongate and close, allowing for the water to become sprayed onto the **chamber** walls. While it may enable better contact between the soil and rinse water to allow cleaning of the chamber surfaces, valve actuation does not fully flood the valve chamber when the valve is actuated closed. The valve chamber of RDVs is significantly larger than the inlet and outlet tubing diameters, resulting in reduced rinse velocity in the wider region in the valve. PBM balanced the need to attain full cleanability of its RDV with its inherent design, as *ASME BPE-2016* Section SD-2.4.2(b)(2) requires the valve to be free of areas of low flow and velocity where soil or contaminants could collect.

Drainability

Figure 2 provides a graphical view of the drainability of the PBM RDV as compared to the ¼" per 12" (1.2°) inclined pipe (per *ASME BPE-2016*). As displayed, the RDV holdup is consistent across the five sizes – it ranges from 0.02 to 0.07 ml/in^2 (with a standard deviation of 0.06), unlike that of the pipes, which ranges from 0.03 to 0.36 ml/in^2 (with double the standard deviation of 0.13). Overall, PBM RDV drainability results show: ½" and 3" RDVs are *more* drainable and 1", 1½", and 2" RDVs are *similarly* as drainable.

Figure 2 (Hold-Up in PBM Igenix® RDVs versus ¼" per 12" Inclined Pipe)



Moving to PBM's Igenix® RDV

How do you make a change in your facility to PBM's Igenix® RDV? If a processor is already using another bottom outlet valve, the biggest obstacle is the change control process. The Igenix® RDV is better with its ability to self-drain similar to or better than *ASME BPE-2016* requirements (a pipe inclined at ¼" per foot) and to be cleanable; compared to its competition, PBM's RDV is as cleanable and is more drainable. For these reasons, the processor should validate the Igenix® RDV – the results are process improvements due to cost savings and fewer quality issues.

To retrofit from existing designs to PBM's Igenix® RDV, PBM could ship the weld pad to the fabricator for new installations. The PBM Igenix® RDV is customizable with different geometries available (**Figure 3**). Custom-fit copper chill block fixtures are available to facilitate welding of PBM's Radial Diaphragm tank outlet valve weld pad. The weld pad easily detaches with a simple hygienic clamp. In time-critical cases,

PBM can ship the weld pad to the fabricator prior to production of the valve, saving time in the fabrication schedule.

CONCLUSION

Media becomes entrapped in bioprocess bottom outlet valves during routine process operations. Cleanability testing has concluded that a typical, routine cleaning cycle should effectively clean all sizes of the PBM Igenix® RDV (Silicone diaphragm) in most cases. A minimum cleaning cycle is warm (65°C) water at turbulent flowrates (5 feet/second) with up to 12 valve actuations over eight minutes. A typical cleaning cycle like *ASME BPE's* CIP cycle cleans all sizes of the Igenix® RDV valve.

The PBM Igenix® RDV (Silicone diaphragm) is *more drainable* than a pipe inclined at ¼" per 12" (1.2°) inclined pipe (*ASME BPE-2016*) in sizes ½" and 3" and is similar in the 1" through 2" sizes. Additionally, testing showed that PBM's 1½" RDV is four times more drainable than its biggest competitor.

For more information on our Igenix® RDV, contact us at:

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