

PennTech Newsletter

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Quote of the Week

"Most people treat the present moment as if it were an obstacle that they need to overcome. Since the present moment is Life itself, it is an insane way to live "... Eckhart Tolle

Next Weeks Topic

* Validation of Vials After Washing *

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Understanding Vial Washer Efficiency...

Often the question is asked: "How much water (WFI) does your washer use per hour?" A simple question with insufficient information to be answered. The correct question is: "What is the minimum amount of WFI at 80° C at a pressure of 5 bar for a 10ml vial on a RW -800 with a WFI-recirculating package and intermittent spraying?" Obviously, the question knows many variations.

The customer's objective is to validate the washing process with the least amount of WFI. We can help the customer to understand the factors involved in the validation process.

Factors are:

- Vial size (a larger vial requires more water than a smaller one).
- Water pressure (the higher the pressure the higher the water flow)
- Washing time (the longer the washing time the higher the water consumption)

There are other factors, such as water temperature and the quality of the glass that may affect the amount of WFI required for the validation.

Let us try to answer the specific question mentioned above. We know that the RW -800 hold six 10ml vials per vial holder (cassette). The orifice diameter in the spray manifold is 1.1mm. The diagram below shows that at 5 bar, each 1.1mm orifice uses 1.47 liter/min. and each 1mm orifice 1.22 liter/min.

At station 5 and 6 of the washing program (thus a machine with optional recirculation package) there are six 1.1mm orifices (for internal spraying) and two 1mm orifices (for external spraying). If we apply a spraying time 1 sec., than the calculation is as follows:

$(6 \times 1.47/60) + (2 \times 1.22/60) = 188$ ml per station containing 6 vials. For both stations 5 and 6 the usage per vial is: $(188 \times 2)/6 = 63$ ml/vial.

If the vials pass the validation test, lower the pressure to 4 bar. The WFI consumption drops to 55 ml/vial. Again, we can reduce the spraying time to 0.75 sec. The water consumption will now be 41 ml.

The bottom line is that the water consumption has to be determined empirically per vial size; in other words during the machine's validation.

Due to the combination of different size orifices for different vials, electronically adjustable intermittent spraying and adjustable water pressure per vial size, the RW-series of vial washers..... the most efficient on the market.

