

To whom it may concern,

Supply of the current Shell Ondina EL oil used in the range of Valairdata integrity test instruments has been made obsolete from the manufacturer. In response to this, Parker domnick hunter will implement the use of an alternative oil, Purity™ FG W015.

It is with regret that this notification is being delivered at short notice and Parker domnick hunter apologise for any inconvenience this may cause.

Purity™ FG W015 is a white mineral oil which is approved to the same standards as Shell Ondina EL (FDA 21 CFR 172.878 and FDA 21 CFR 178.3620) and has closely matched physical properties to the Shell Ondina EL oil.

A thorough design verification of the new oil has taken place to support the change. Results show that the performance and accuracy of the Valairdata units are identical with both oils when testing sterile gas filters which utilise both media and membrane filter materials.

In addition, particle size analysis work has shown that the particle size distributions between Shell Ondina EL and Purity™ FG W015 are comparable at the rated gas pressure and flow utilised by the Valairdata aerosol generators.

In summary, this design verification output has shown that the accuracy and repeatability of the Valairdata integrity test units is not affected by changing to the new Purity™ FG W015 oil.

#### Validation Details

The supplier of the new oil has assured Parker domnick hunter of equivalence, however in order to ensure that the change does not affect Valairdata performance characteristics, a thorough design verification has been carried out.

Test Validation	Acceptance Criteria
Safety	No toxicological hazards
Compliance	To be compliant to FDA 172.878 and 178.3620(a)
Particle Size Analysis	>/= number of particles at 0.3µm at rated pressure of Aerosol Generator
Aerosol challenge accuracy depth filters	Equivalent test results with control oil
Aerosol challenge accuracy membrane filters	Equivalent test results with control oil

**Table 1. Summary of Design Verification Testing**

#### Product Coding

Description	Part Order Code
1L bottle	639504196
10mL syringe	639504197

If you have any further queries about this change, please contact your local Parker domnick hunter representative or e-mail Parker domnick hunter at: [dhprocess@parker.com](mailto:dhprocess@parker.com)

On behalf of Parker domnick hunter,



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