

Independent Test Report

Leakage Testing of Penlon Sigma Delta Vaporisers on Dräger Auto Exclusion Back Bar and GE Selectatec Back Bar

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Dr Tom Clutton-Brock

Methods:

Dräger Perseus A500 anaesthetic machine with pipeline air and oxygen (no N₂O connected), Leak Assistant mode with a constant pressure of 20cm H₂O, < 100 ml/min deemed a pass.

Datex-Ohmeda Aesteva/5 anaesthetic machine with pipeline air and oxygen (no N₂O connected), Evacuated bulb test, vacuum retained for 60 seconds deemed a pass.

O-rings checked and in good condition

Penlon Sevoflurane Sigma Delta Vaporiser, empty

Dräger Sevoflurane Vapor 3000, empty

Datex-Ohmeda Isotec 5, empty

Order of testing: Empty back bar, Vapor / Isotec / Sigma Delta off, Vapor / Isotec / Sigma Delta on, Vapor / Isotec / Sigma Delta on with filler open (to confirm that a leak could be detected).

Vapor / Isotec with Sigma Delta to confirm interlock works correctly, both combinations of off / on tested.

Sony FS5 4k video of procedures, original footage retained.

Results:

Machine	State	Leak
Perseus A500	Empty Back Bar	≈ 100 ml/min. Pass
Perseus A500	Dräger Vapor 3000 off	≈ 100 ml/min. Pass
Perseus A500	Dräger Vapor 3000 on	≈ 100 ml/min. Pass
Perseus A500	Dräger Vapor 3000 on, filler open	> 1500 ml/min
Perseus A500	Penlon Sigma Delta off	≈ 100 ml/min. Pass
Perseus A500	Penlon Sigma Delta on	≈ 100 ml/min. Pass
Perseus A500	Penlon Sigma Delta on, filler open	> 1500 ml/min
Perseus A500	Dräger Vapor + Penlon Sigma Delta	Interlock passed in both combinations
Datex-Ohmeda Aesteva/5	Empty Back Bar	None detected
Datex-Ohmeda Aesteva/5	Datex-Ohmeda Isotec 5 off	None detected
Datex-Ohmeda Aesteva/5	Datex-Ohmeda Isotec 5 on	None detected
Datex-Ohmeda Aesteva/5	Datex-Ohmeda Isotec 5 on, filler open	Leak ++
Datex-Ohmeda Aesteva/5	Penlon Sigma Delta off	None detected
Datex-Ohmeda Aesteva/5	Penlon Sigma Delta on	None detected
Datex-Ohmeda Aesteva/5	Penlon Sigma Delta on, filler open	Leak ++
Datex-Ohmeda Aesteva/5	Dräger Vapor + Penlon Sigma Delta	Interlock passed in both combinations

Conclusions:

The test results established compatibility of Penlon Sigma Delta vaporisers when used with GE Selectatec and Dräger Auto Exclusion Anaesthesia machines.

In particular, Penlon Sigma Delta vaporisers make gastight connections, the interlock system works correctly, and the function of the anaesthetic machine is not affected.



Dr Tom Clutton-Brock FRCP FRCA FFICM

Clinical Director, NIHR Trauma Management MedTech Cooperative
 Clinical Director, ERDF Medical Devices Testing and Evaluation Centre
 Deputy Director, Institute of Translational Medicine, Birmingham
 Reader in Anaesthesia & Intensive Care Medicine