MTGR integrity test

Multiple positions manifold

Test simultaneously 5 to 10 filters with the alcohol based bubble point test.

Testing approach validity

Parallel testing of aervent 50 capsules:
Testing multiple aervent 50 on a manifold with the bubble point test is an acceptable practice since it is identical to testing multiple filter cartridges in a multi-round housing. This is a standard industry practice, well documented in the PDA technical reports 26 and 40 on sterilizing filtration of liquids and gas.

The intregity test must ensure that :

The test is senstive to detect a damaged filter among the other ones.
The test is accurate.
The filter traceability is ensured.

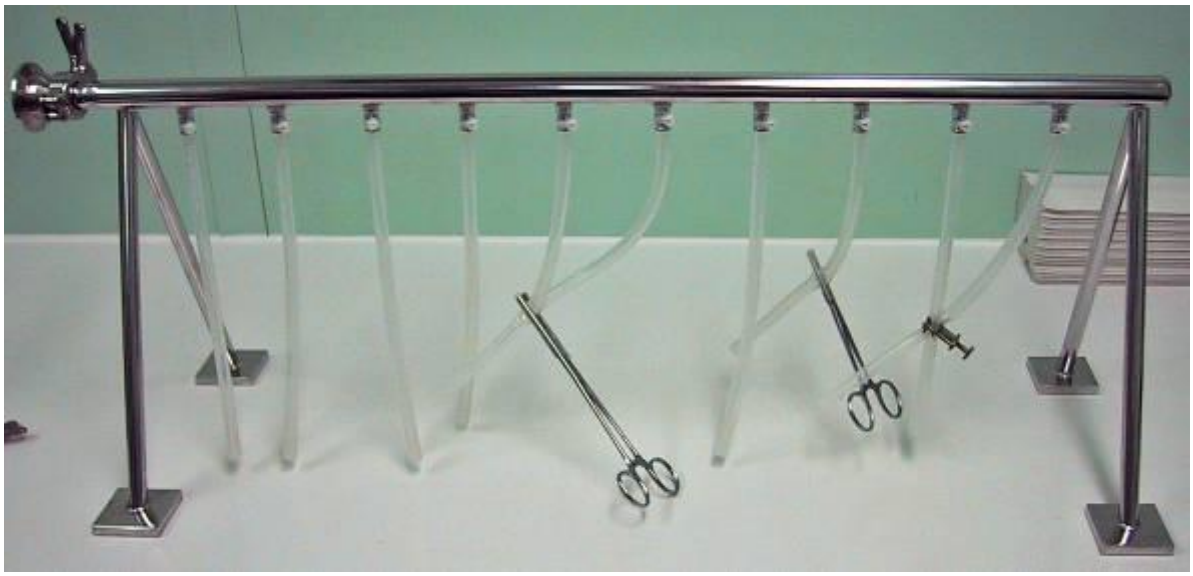
Discussion:

1. The sensitvity is ensured by the bubble point test which is a measurement of the largest pore/smallest defect of the system and is independant to the system size.
(minimum bubble point specification is 1.1 bar with IPA/water 60/40 mixture)
A bubble point measure of 1.5 bar due to one filter reaching the bubble point at this pressure is a guaranty that the filter is integral and that all other filters have a bubble point higher than 1.5 bar and are integral.
A bubble point measure of 0.5 bar due to one defective filter should trigger the testing of the filters individually to identify the failing one.
This sensitivity test is easily verified during the IQOQ of the tester and the manifold.

2. Test accuracy is verified during the on-site qualification of the automatic instrument by the comparison of the test in parallel with a reference method (visual detection + reference pressure gauge).

3. Filter traceability is ensured by organizing the flow of vent capsules in the department, and by their indentification with the unique combination of lot number and serial number.
documenting different serial number on the same test report is acceptable.

With hose barb connection



With sanitary TC connection

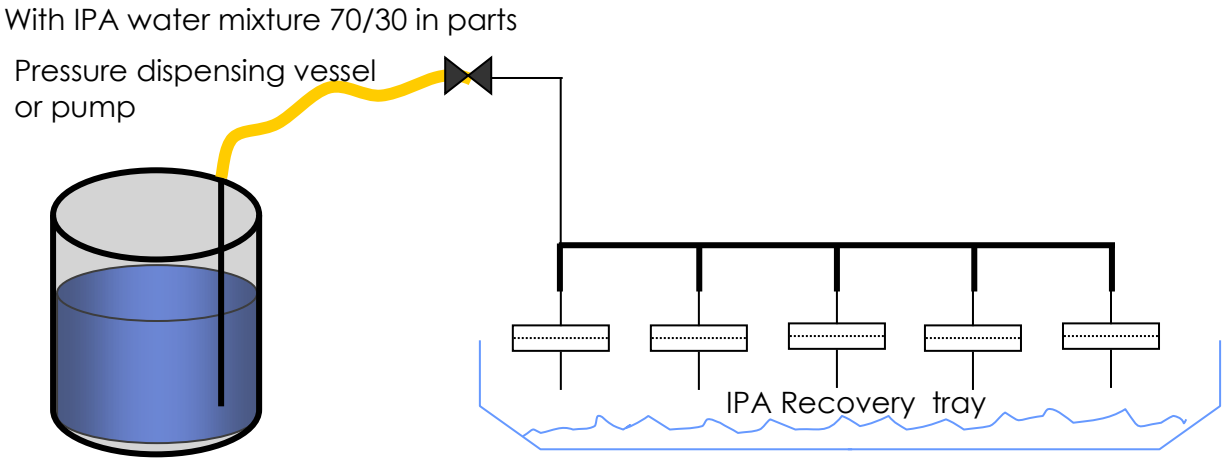
¾"TC Manifold allows for the testing of 50mm air filters with the following configurations:

¾" TC	Luer	Hose	¾" TC
MTGR15000	MTGR85000	MTGR85000	Stopper
MTGR25000	MTGR05000	MTGR05000	

Utilization

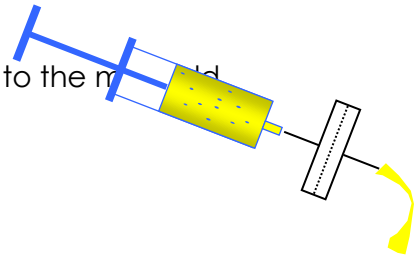
Filter wetting

With a pump or a pressure dispensing vessel

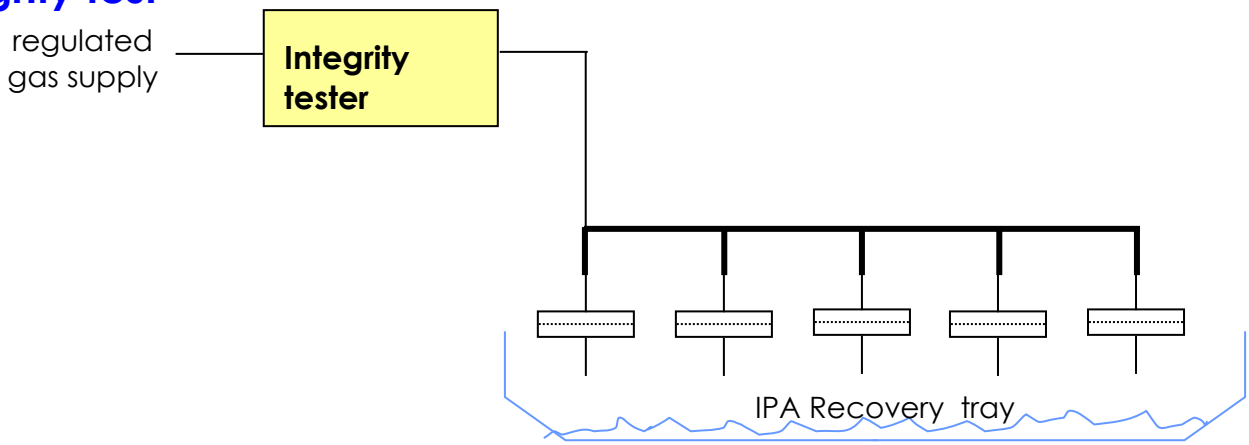


Manually with a syringe

Wet individually the Aervent 50 with a syringe prior to connect to the m

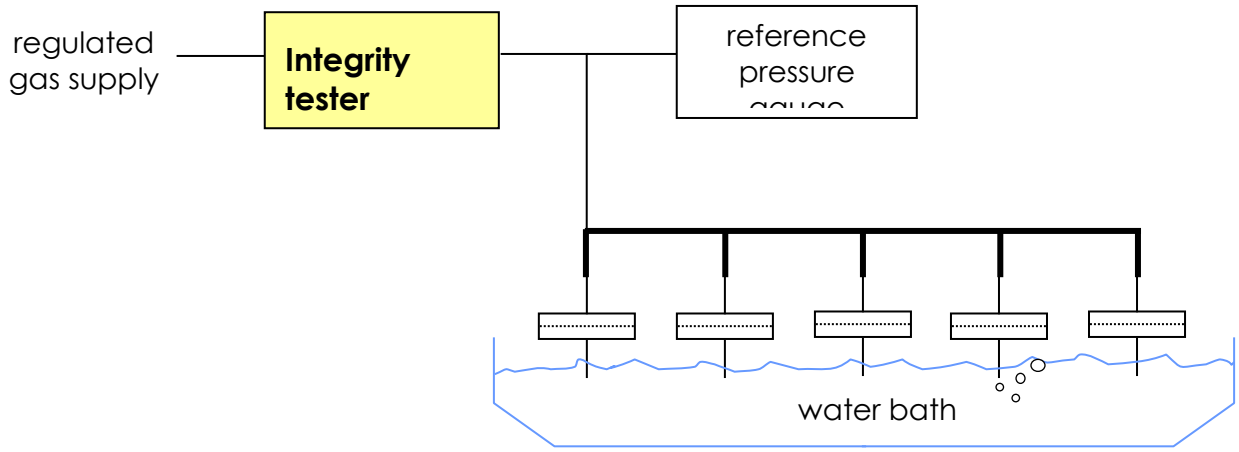


Integrity test



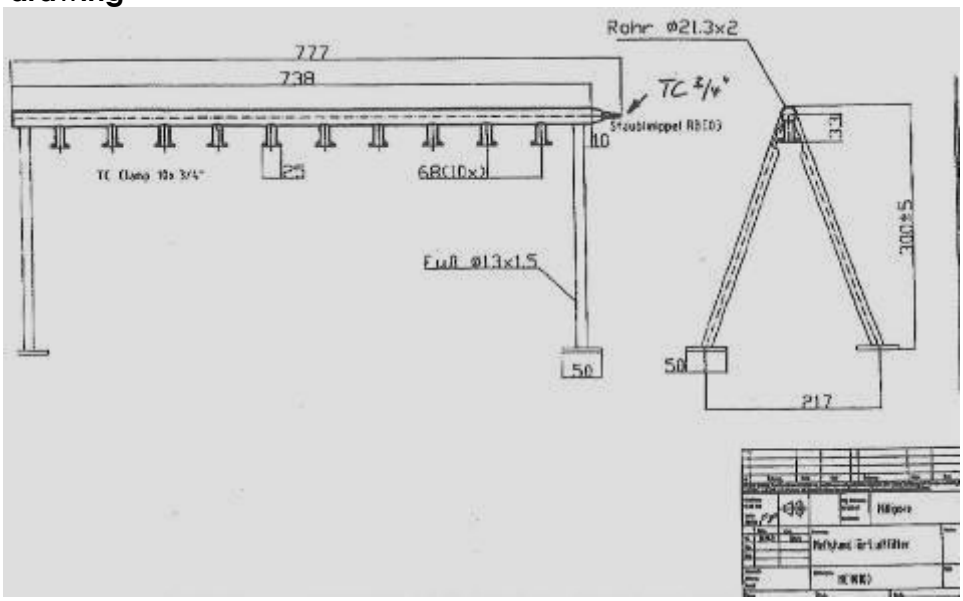
Qualification

Simultaneous automatic and manual filter test set-up for qualification purpose



References

Manifold drawing



ManifofdPrince : about 1500 €

Accessories

	Reference	Description
	JMSZ50553	as described in DB (3/4" TC ISO DN8)
	FTPF01893	Clamp 3/4" TC - stainless steal
or	3538200WB	Clamp 3/4" TC - plastic
	MS0TC3403	Adaptator for sampling port TC 3/4"-10 pieces
	to be created	Gaskets EPDM
	to be created	3/4" TC blindcap
	Total 1	stainless steal
	Total 2	plastic clamp