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1. ABSTRACT

This report summarizes the filter compatibility testing of C and EC smoke evacuation connectors (part numbers 2150 and 2155). Testing was conducted per protocol XENG-PRT-438, with deviations noted in this report.

2. REFERENCES

XENG-PRT-438	PROTOCOLFILTER FIT COMPATIBILITY TEST, ZIP-PEN SMOKE EVACUATION CONNECTORS
ENG-PRT-438	PROTOCOL, FILTER FIT COMPATIBILITY TEST, ZIP-PEN SMOKE EVACUATION CONNECTORS

3. METHODS AND SETUP

See XENG-PRT-438. The protocol was followed exactly with the following changes:

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SCOPE ADDITIONS:

Due to marketing requests following the release of the test procedure, a few filters were added to the Scope and were tested following the same procedure. NOTE: Addition 3 and 4 took place following the original test date, and testing for those filters took place at a later date.

Addition 1: The LINA Safe Air ULPA filter was added to the Scope for the EC Connector (2155). The same testing procedure was used.

Addition 2: The Medtronic RapidVac™ Valley Lab filter was added to the Scope for the C Connector. The same testing procedure was used.

Addition 3: The MEGADYNE MINIVAC™ (ECVV120 AND ECVV220), MicroSafe Filter (MGVS35302), and MicroSafe Filter Fluid Trap (MGVSFT10) was added to the Scope for the EC Connector (2155). The same testing procedure was used.

Addition 4: The Stryker Neptune® was added to the Scope for the EC Connector (2155) when in use with the MicroSafe Filter Fluid Trap (MGVSFT10). The same testing procedure was used.

Addition 5: The MEGADYNE In-Line Filter (2330) was added to the Scope for the C Connector (2150). The same testing procedure was used. However, direct connection of the C Connector to the In-line Filter does not represent the actual use of the device. A fluid canister must always be present between the Filter and Connector. Therefore, the In-Line Filter is not included in the final compatibility list.

PROTOCOL DEVIATIONS:

A few minor deviations from the original protocol took place as described below.

Deviation 1: When used with the MEGADYNE MINIVAC™ (ECVV120 AND ECVV220) with MicroSafe Filter Fluid Trap (MGVSFT10), the C Connector (2150) requires the use of the 22 mm Tube Adapter (2151) (Figure 1). The C Connector is compatible with the MicroSafe Filter (MGVS35302) without the use of the 22 mm Tube Adapter. Therefore, the connector is deemed compatible with the MEGADYNE MINIVAC™ system.



Figure 1: 22 mm Adapter and C connector

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Deviation 2: In XENG-PRT-438, MEGADYNE® 500 (2400) was listed instead of MEGADYNE MEGAVAC™ Max (2400). The two names refer to the same product. The final table under RESULTS refers to the unit as MEGADYNE MEGAVAC™ Max (2400). This name update did not affect any testing.

NON-CONNECTOR RELATED DISCONNECTS DEEMED ACCEPTABLE:

In four test cases, other connection points of the set up disconnected prior to the convoluted tubing extending. These were deemed passes, as the C or EC connector were not the first to fail. If the C or EC connector remained attached following the disconnect at a different location (fluid trap, other connector in system), the pull test was deemed a PASS.

Non-Tubing Failure 1: When pull testing the MicroSafe Filter Fluid Trap (MGVSFT10) with the C Connector (2150), the fluid trap released from the MEGADYNE MINIVAC™ before the convoluted tubing broke. This failure mode was not anticipated, but was deemed a PASS as the C connector remained attached.

Non-Tubing Failure 2: When pull testing the MicroSafe Filter Fluid Trap (MGVSFT10) + Stryker Neptune® filter with the EC Connector (2155), the fluid trap released from the Stryker Neptune® filter before the convoluted tubing broke. This failure mode was not anticipated, but was deemed a PASS as the EC connector remained attached.

Non-Tubing Failure 3: When pull testing the MicroSafe Filter Fluid Trap (MGVSFT10) with the EC Connector (2155), the fluid trap released from the MEGADYNE MINIVAC™ before the convoluted tubing broke. This failure mode was not anticipated, but was deemed a PASS as the EC connector remained attached.

Non-Tubing Failure 4: When pull testing the MEGADYNE in-line filter (2330) with the C Connector (2150), the non-ZIP PEN connector of the in-line filter assembly disconnected before the convoluted tubing broke. This failure mode was not anticipated, but was deemed a PASS as the C connector remained attached.

These deviations are the only changes in how XENG-PRT-438 was executed.

4. RESULTS

4.1. The connector/filter configurations listed in Table 1 below passed the required pull tests and visual tests for compatibility. The connector/filter configurations

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listed in Table 2 failed either the required pull tests and/or visual tests for compatibility. See Appendix A for all original test data.

Table 1: Connectors and Compatible Smoke Evacuation Filters/Systems that PASSED both a pull test and a visual test

Note: The corresponding test order number is indicated in parentheses before the filter/fluid type name.

Connector Part #		
2150		2155
Compatible Filters	MEGADYNE MEGAVAC™ (2100J) with - (1) ULPA Filter with Fluid Trap (2210J) - (2) ULPA Filter (2211J)	MEGADYNE MINIVAC™ (ECVV120 and ECVV220) with - (20) MicroSafe Filter (MGVS35302) - (21) MicroSafe Filter Fluid Trap (MGVSFT10)
	Ethicon MEGADYNE™ Smoke Evacuator (MESE1) with - (3) MegaFilter (2550J) - (4) Fluid Trap (2555J)	(12) Buffalo Filter Viro Vac® with - Viro Safe Filter
	MEGADYNE MEGAVAC™ Plus (2200J) with - (5) ULPA Filter with Fluid Trap (2210J) - (6) ULPA Filter (2211J)	(13) Buffalo Filter VisiClear®
	MEGADYNE MINIVAC™ (ECVV120 and ECVV220) with - (8) MicroSafe Filter (MGVS35302) - (7) MicroSafe Filter Fluid Trap (MGVSFT10)*	(15) Erbe IES
	(9) ConMed AER DEFENSE™	(19) Stryker Neptune® (compatible with use of MGVSFT10 fluid trap only)
	(10) Buffalo Filter Viro Vac® with - Viro Safe Filter	(17) LiNA Safe Air with - ULPA Filter
	(11) Buffalo Filter VisiClear®	
	(18) Medtronic RapidVac™ with - ValleyLab Filter (Metal Front Plate filter ONLY see Appendix C)	

* Compatible only with addition of 22 mm Adapter (2151)

Table 2: Connectors and Smoke Evacuation Filters/Systems that FAILED either a pull test and/or visual test

Note: Corresponding test order number found in parentheses preceding filter/fluid type name.

Connector	Filter	Pull Test	Visual Test
2155	(14) Medtronic RapidVac™ with - ValleyLab Filter	FAIL	FAIL

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	(16) Stryker Neptune® (tube only)	FAIL	PASS
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5. CONCLUSION

- 5.1. The C Connectors (2150) and EC Connectors (2155) passed the testing per protocol XENG-PRT-438 for determining connector compatibility for the filters/fluid traps listed in Table 1. Both a Pass/Fail pull test in which the convoluted tubing breaks/extends prior to connector removal, as well as a Pass/Fail visual inspection were used to determine compatibility. The EC Connector (2155) failed either the pull test and/or visual test per protocol XENG-PRT-438 for the Medtronic RapidVac ValleyLab filter and Stryker Neptune tube only configuration, listed in Table 2. The EC connector was not designed to fit either of these filters. Therefore, it is still determined that both the C and EC connectors are compatible with all intended filters at the time of original design.

The C and EC connectors are used in several smoke evacuation pencils and accessories. The testing performed here deems each connector compatible with specified filters as summarized in Table 1. This compatibility extends to smoke evacuation products beyond the ZIP PEN to which this testing was performed, if the same connector is used with the same smoke evacuation accessory.

This procedure may be used in determining compatibility of future smoke evacuation connectors and future smoke evacuation systems as they become available. Appendix B outlines specific filters used in testing. Note that competitive smoke evacuation systems may change filter port designs, which in the future will require further testing should the design change the fit of the connector.

6. APPENDIX A – TESTING DOCUMENT

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DATA SHEET									
Test Order	ZIP-PEN Lot Number	Connector Type	Connector Lot Number	Filter / Fluid Trap Type	Filter / Fluid Trap Serial & Lot Number	Visual Inspection Pass/Fail	Pull Test Pass/Fail	Notes	
1	L#:S160577	2150	CONSULT LOT HISTORY OF ZIP-PEN FOR CONNECTOR LOT #'S						
2	L#:S160577	2150							
3	L#:S160577	2150							
4	L#:S160577	2150							
5	L#:S160577	2150							
6	L#:S160577	2150							
7	L#:S160577	2150							
				ULPA Filter with Fluid Trap	S#: NA L#: 6454	P	P	NA	
				ULPA Filter	S#: NA L#: 15169	P	P	NA	
				Mega Filter	S#: NA L#: 18243	P	P	NA	
				Mega Filter with Fluid Trap	S#: NA L#: S160586	P	P	NA	
				ULPA Filter with Fluid Trap	S#: NA L#: 6454	P	P	NA	
				ULPA Filter	S#: NA L#: 15169	P	P	NA	
				MicroSafe Filter fluid trap	S#: NA L#: 17519 L#: 12 NA	P	P	Used with 2151 Tube Adapter Fluid trap disconnects from Filter before tubing extends	ETT

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CONSULT LOT HISTORY OF ZIP-PEN FOR CONNECTOR LOT #'S									
8	L#:S160577	2150	MicroSafe Filter	S#: NA L#:126356	P	P	NA		
9	L#:S160577	2150	ComMed AER DEFENSE	S#: NA L#:020614	P	P	NA		
10	L#:S160577	2150	Viro safe Filter	S#: NA L#:122476	P	P	NA		
11	L#:S160577	2150	Buffalo Filter VisiClear	S#: NA L#:129191	P	P	NA		
12	L#:S150346	2155	Viro safe filter	S#: NA L#:122476	P	P	NA		
13	L#:S150489	2155	Buffalo Filter VisiClear	S#: NA L#:129191	P	P	NA		
14	L#:S150489	2155	ValleyLab Filter	S#: NA L#:101505	F	F	connector does not fit into filter		
15	L#:S150489	2155	Erbe TES	S#: NA L#:1430000100- 00978-2014-06	P	P	NA		
16	L#:S150346	2155 (tubing only)	Stryker Neptune®	S#: NA L#:S120590114	P	F	Tubing fits into filter but dis connects before hooking extend		

LT

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Tested by:

Name: Eric Tyler

Signature: Eric Tyler

Date: 09/29/17

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DATA SHEET									
Test Order	ZIP-PEN Lot Number	Connector Type	Connector Lot Number	Filter / Fluid Trap Type	Filter / Fluid Trap Serial & Lot Number	Visual Inspection Pass/Fail	Pull Test Pass/Fail	Notes	
17	L#: 50489	2155	CONSULT LOT HISTORY OF ZIP-PEN FOR CONNECTOR	LiNA	S#: NA L#: 121102	P	P	NA	

Tested by:

Name: Eric Tyler

Signature: Eric Tyler

Date: 09/29/17

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DATA SHEET							
Test Order	ZIP-PEN Lot Number	Connector Type	Connector Lot Number	Filter / Fluid Trap Type	Filter / Fluid Trap Serial & Lot Number	Visual Inspection Pass/Fail	Pull Test Pass/Fail
18	L#: 6160577	2150	CONSULT LOT HISTORY OF ZIP-PEN FOR CONNECTOR LOT #'S	ValleyLab filter	S#: NA L#: 101505	P	P
							NA

Tested by:

Name: Eric Tyler

Signature: *Eric Tyler*

Date: 09/29/17

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DATA SHEET							
Test Order	ZIP-PEN Lot Number	Connector Type	Connector Lot Number	Filter / Fluid Trap Type	Filter / Fluid Trap Serial & Lot Number	Visual Inspection Pass/Fail	Pull Test Pass/Fail
19	L#:5150489	2155	CONSULT LOT HISTORY OF ZIP-PEN FOR CONNECTOR LOT #'S				^{ERT} F P
				MicroSafe Filter Fluid trap with strainer	S#: NA L#: 127519	P	Fails when tubing is pulled to the side - ERT fluid trap disconnects from filter when pulled to the sides
20	L#:5150489	2155		Micro Safe Filter	S#: NA L#: 126356	P	NA
21	L#:5150489	2155		Micro safe Filter with fluid trap	S#: NA L#: 127519	P	Fluid trap disconnects from filter before tubing extends
22	L#:5160577	2150		In line filter	S#: NA L#: 105018	P	In line filter connector fails before the tubing extends

Tested by:

Name: Eric Tyler

Signature: Eric Tyler

Date: 10/05/17

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7. APPENDIX B: TEST FILTER INFORMATION

- 7.1. Figure 2 shows all non-Megadyne filters tested in this study, with the corresponding test order number found in parentheses preceding filter/fluid type name. Drawings of all Megadyne filters and accessories tested can be found in the internal document control system.



Figure 2: (15) Erbe IES



Figure 3: (16, 19) Stryker Neptune®

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Figure 4: (14, 18) Medtronic RapidVac with ValleyLab Filter

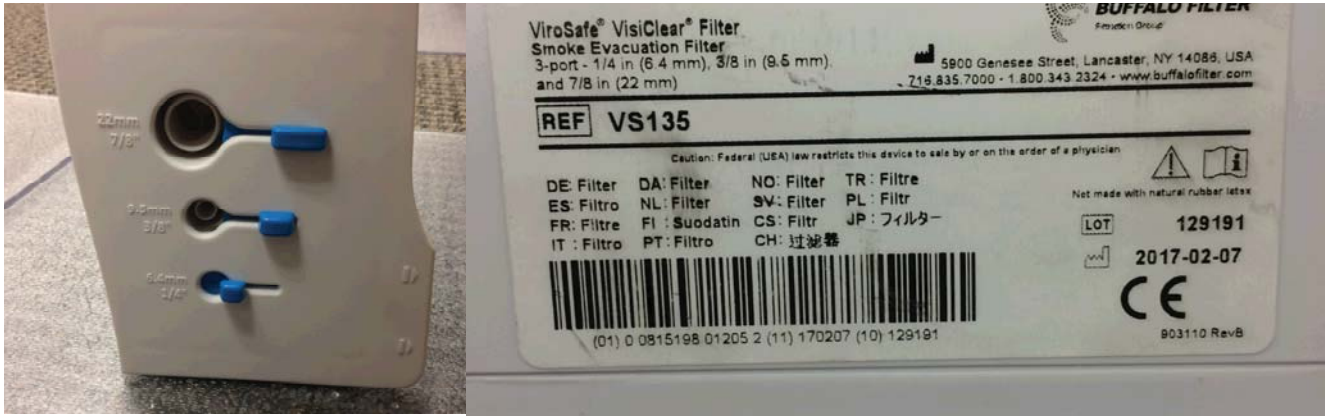


Figure 5: (11, 13) Buffalo Filter VisiClear®

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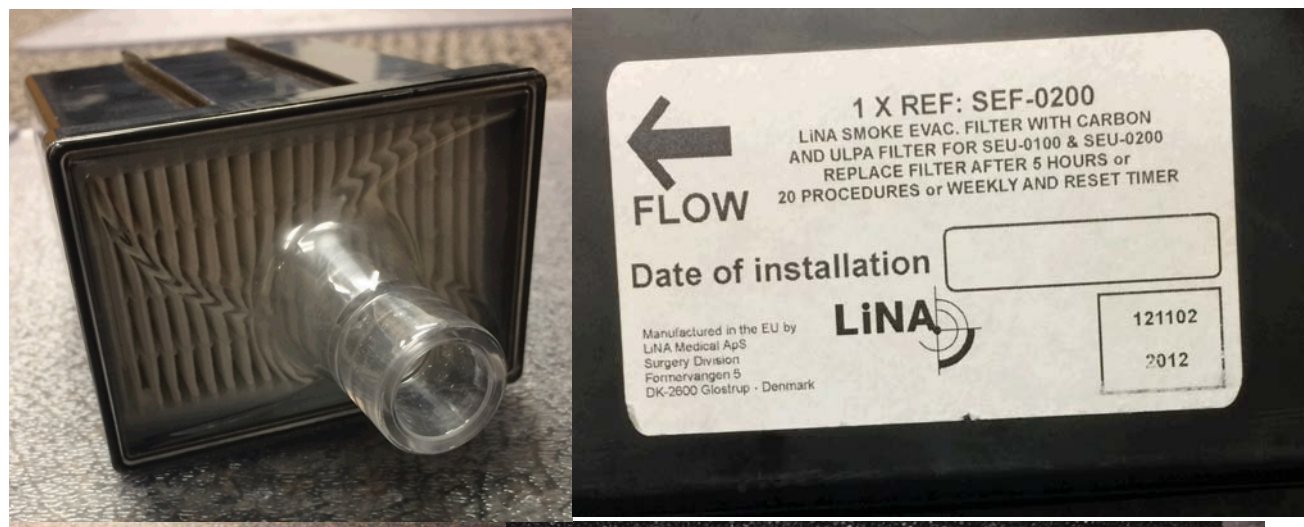


Figure 6: (17) LiNA Safe Air with ULPA Filter



Figure 7: (9) ConMed AER DEFENSE



Figure 8: (10, 12) Buffalo Filter Viro Vac® with Viro Safe Filter

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8. APPENDIX C: RAPIDVAC FILTER CONFIGURATIONS



Figure 9: RapidVac Filters. Note that only the metal front plate RapidVac filter is compatible with the C connector (left). The newer Rapid Vac filter (same product code; SEA3700) is not compatible with the C connector (right).