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Filter Fit Compatibility

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1. REFERENCES

3000317-01	IFU, MEGADYNE ZIP w/ ACE BLADE 700
3000312-01	IFU, Zip Pen
ENG-RMF-045	Smoke Evacuation Risk Analysis
ENG-RPT-329	Zip Pencil Mechanical

2. SCOPE

This procedure applies to testing filter fit compatibility of the Megadyne ZIP-PEN smoke pencil adapters. This procedure examines specifically the fit of the ZIP-PEN Universal Adapter/C Connector (part number 2150) and EC Connector (part number 2155) to the smoke evacuation systems, filters, and fluid traps found in Table 1. Connectors 2150 and 2155 are part of the assembly on Cat Numbers 2525-10, 2525-10EC, 2525-10BN, and 2525-10ECBN (ZIP PEN), as well as ME7251C, ME7251E, ME725M1C, and ME725M1E (ZIP ACE).

Table 1: Connectors and Compatible Smoke Evacuation Filters/Systems

	Connector Part #	
	2150	2155
Compatible Filters	MEGADYNE MEGAVAC™ (2100) with - ULPA Filter with Fluid Trap (2210) - ULPA Filter (2211)	Buffalo Filter Viro Vac® with - Viro Safe Filter
	MEGADYNE® 500 (2400) with - MegaFilter (2550) - Fluid Trap (2555)	Buffalo Filter VisiClear®
	MEGADYNE MEGAVAC™ Plus (2200) with - ULPA Filter with Fluid Trap (2210) - ULPA Filter (2211)	Erbe IES
	MEGADYNE MINIVAC™ (ECVV120 and ECVV220) with - MicroSafe Filter (MGVS35302) - MicroSafe Filter Fluid Trap (MGVSFT10)	Medtronic RapidVac™ with - ValleyLab Filter
	ConMed AER DEFENSE™	Stryker Neptune® (compatible with tubing only)
	Buffalo Filter Viro Vac® with - Viro Safe Filter	
	Buffalo Filter VisiClear®	

3. PURPOSE

This procedure defines the method for testing fit compatibility of ZIP-PEN smoke evacuation connectors with MEGADYNE smoke evacuation systems and filters as well as competitor smoke evacuation systems and filters (listed in Table 1) to ensure secure attachment.

The purpose of this procedure is not to evaluate variation of connector dimensions among a given lot, but to be a qualitative assessment of whether a given connector attaches to a given smoke evacuation filter or fluid trap, and remains attached during reasonable use. A visual inspection and a qualitative pull test will be used to evaluate attachment. There is no current specification for fit of ZIP-PEN connectors.

4. RISK ASSESSMENT

The ZIP-PEN is designed with long, 10 ft tubing that seldom sees full tension during use. In the event of unlikely tension, the convoluted tubing allows for stretching of the tubing. The design of the ZIP-PEN is such that the cable attached to an ESU is shorter than the tubing attached to the smoke evacuator. Therefore, in a typical use scenario, should the entire 10ft length of the device be extended, the ZIP-PEN cable will become unplugged from the ESU prior to the connector becoming unplugged from the smoke evacuator (Figure 1). In the unlikely event the connector becomes disconnected, the risks include customer dissatisfaction, as well as the potential for release of remnant smoke still in the tubing prior to disconnection form the smoke evacuator.

Figure 1: Typical ESU/Smoke Evacuator setup. Slack in ZIP PEN tubing when cable sees full tension.

There are 0 complaints in the field in the past year regarding smoke evacuator connectors from the time of this study, from August 2016 through August 2017. Per ENG-RMF-045, from August 2011 through July 2014, Megadyne received 5 Fit/Connection Complaints concerning smoke evacuation products (Ultra Vac), with a complaint rate of 0.0011%, confirming 0 of these complaints with a confirmed rate of 0.0000%.

The Smoke Evacuation FMEA was reviewed for any line items applicable to connector incompatibility. Failure modes include:

- Connector does not fit or disconnects easily, leading to customer dissatisfaction (item 32-d)
- Connector incompatible with other equipment, leading to no smoke collection and customer dissatisfaction (item 33-d)

These risks are mitigated through specifying compatible equipment, as determined by this protocol, and through designing connectors compatible with industry accepted filter / fluid trap interfaces.

5. REQUIRED TOOLS & EQUIPMENT

5.1. Smoke Evacuator Filters / Fluid Traps (1 EA)

5.1.1. MEGADYNE MEGAVAC™ Smoke Evacuation System (part number 2100)

5.1.2. MEGADYNE® 500 (part number 2400)

5.1.2.1. MegaFilter (part number 2550)

5.1.2.2. Fluid Trap (part number 2555)

5.1.3. MEGADYNE MEGAVAC™ Plus (part number 2200)

5.1.3.1. ULPA Filter with Fluid Trap (part number 2210)

5.1.3.2. ULPA Filter (part number 2211)

5.1.4. MEGADYNE MINIVAC™ Smoke Evacuation System (ECVV120 or ECVV220)

5.1.4.1. MicroSafe Filter (part number MGVS35302)

5.1.4.2. MicroSafe Filter Fluid Trap (part number MGVSFT10)

5.1.5. ConMed AER DEFENSE™

5.1.6. Buffalo Filter Viro Vac®

5.1.6.1. Viro Safe Filter

5.1.7. Buffalo Filter VisiClear®

5.1.8. Erbe IES Filter

5.1.9. Medtronic RapidVac™

5.1.9.1. ValleyLab Filter

5.1.10. Stryker Neptune®

5.1.10.1. Smoke Evacuator ULPA Filter

5.2. ZIP-PEN Smoke Evacuation Pencils (10 ft Cord Length) (part number 2525-10)

5.2.1. NOTE: This product comes with a C connector (part number 2150) (Figure 2.1)

5.3. ZIP-PEN Smoke Evacuation Pencils (10 ft Cord Length), 22mm Connector and Holster (part number 2525-10EC)

5.3.1. NOTE: This product comes with an EC connector (part number 2155) (Figure 2.2)

5.4. 25 lb weight

Figure 2: Connectors

6. PROCEDURE

Requirement:

A minimum sample size of 1 will be used per filter/connector combination.

As previously stated, the purpose of this protocol is not to evaluate variation of connector dimensions among a given lot, but to be a qualitative assessment of whether a given connector attaches to a given smoke evacuation filter or fluid trap, and remains attached during reasonable use. This is a qualitative assessment that should not vary significantly between connectors of the same design. This is a low risk item, and the aggregate of filters tested with similar connector ports will allow for larger assessment of fit.

Test Procedure:

6.1. C Connector Testing

6.1.1. Obtain ZIP-PEN (part number 2525-10) and record its lot number in the data sheet found in Appendix A.

6.1.2. Obtain a filter or fluid trap (listed in Table 1) and record its lot number and serial number (if available) in the data sheet found in Appendix A. If unavailable, write N/A.

6.1.3. Securely attach (as per 3000317-01 IFU, MEGADYNE ZIP w/ ACE BLADE 700) the C Connector to a filter or fluid trap installed in its corresponding smoke evacuator box on a flat surface with ample surrounding space for pull test.

6.1.3.1. NOTE: If filter has multiple ports, ensure that appropriate sized port is used.

6.1.3.2. NOTE: If a corresponding smoke evacuator is unavailable, weigh down the filter with the 25lb weight. (Figure 3)

Figure 3: Erbe Filter with 25lb weight

6.1.4. Visual Inspection

6.1.4.1. Visually inspect the connector and filter / fluid trap interface. If the connector fits (can be inserted / attached and stays in place after placement by operator), it is considered a Pass. If the connector does not fit, it is considered a Failure. Record results in the Visual Inspection column of the data sheet found in Appendix A. See acceptance criteria for example.

6.1.5. Pull Test

6.1.5.1. Grasp the ZIP-PEN mid-tube connector closest to the smoke evacuator, holding the tubing parallel to the ground, without slack and perpendicular to the front face of the filter. (Figure 4)

Figure 4: Starting position prior to pull test

6.1.5.2. From the mid-tube connector, pull straight away from the smoke evacuator until at least 1 section of the convoluted tubing extends. (Figure 5)

6.1.5.2.1. NOTE: Extension may take place at any location along length of tubing, especially near the filter port and near the mid-tube connector.

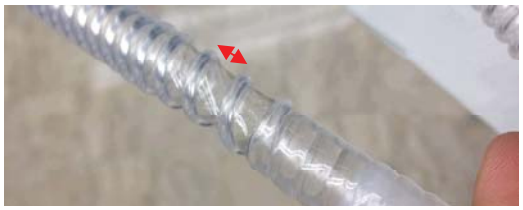

Figure 5: Extension of convoluted tubing

6.1.5.2.2. NOTE: Extension of the convoluted tubing is not intended during typical use, making this an extreme and unlikely force on the connector. It shall be considered worst case.

6.1.5.3. Maintaining the same or similar tension, bring the tubing 90 degrees to the left, and 90 degrees to the right. (Figure 6)

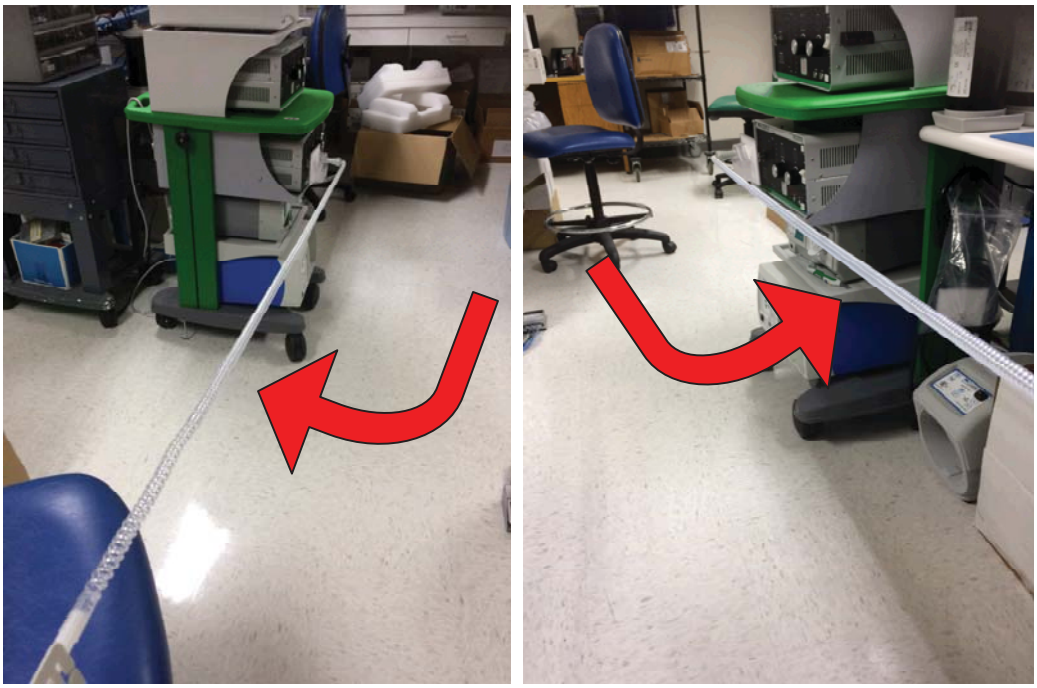

Figure 6: 180 degree pull test

6.1.5.4. If the connector stays attached to the smoke evacuator for the duration of the pull test, it is considered a Pass. If the connector does not stay attached, it is considered a Failure. Record results in the pull test column of the data sheet found in Appendix A.

6.1.6. Repeat steps 6.1.1 through 6.1.5 with the next filter or fluid trap, using a new ZIP PEN for each. Test all filters / fluid traps listed in Table 1 for part number 2150.

6.2. EC Connector Testing

6.2.1. Obtain ZIP-PEN (part number 2525-10EC) and record its lot number in the data sheet found in Appendix A.

6.2.2. Obtain a filter or fluid trap (listed in Table 1) and record its lot number and serial number (if available) in the data sheet found in Appendix A. If unavailable, write N/A.

6.2.3. Securely attach (as per 3000317-01 IFU, MEGADYNE ZIP w/ ACE BLADE 700) the EC Connector to a filter or fluid trap installed in its corresponding smoke evacuator on a flat surface with ample space surrounding for pull test.

6.2.3.1. NOTE: If filter has multiple ports, ensure that appropriate sized port is used.

6.2.3.2. NOTE: If a corresponding smoke evacuator is unavailable, weigh down the filter with the 25 lb weight. (Figure 3)

6.2.3.3. NOTE: In testing Stryker Neptune, carefully remove the EC connector from the end of the convoluted tubing and attach to the 3/8-inch port. (Figure 7)

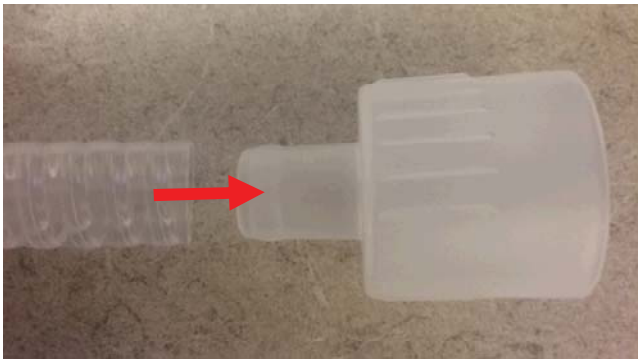

Figure 7: Removal of EC connector from tubing for Stryker Neptune Connection

6.2.4. Visual Inspection

6.2.4.1. Visually inspect the connector and filter / fluid trap interface. If the connector fits (can be inserted / attached and stays in place after placement by operator), it is considered a Pass. If the connector does not fit, it is considered a Failure. Record results in the Visual Inspection column of the data sheet found in Appendix A. See acceptance criteria for example.

6.2.5. Pull Test

6.2.5.1. Grasp the ZIP-PEN mid-tube connector closest to the smoke evacuator, holding the tubing parallel to the ground and perpendicular to the front face of the filter. (Figure 4)

6.2.5.2. From the mid-tube connector, pull straight away from the smoke evacuator until a single section of the convoluted tubing extends. (Figure 5)

6.2.5.2.1. NOTE: Extension may take place at any location along length of tubing, especially near the filter port and near the mid-tube connector.

6.2.5.2.2. NOTE: Extension of the convoluted tubing is not intended during typical use, making this an extreme and unlikely force on the connector. It shall be considered worst case.

6.2.5.3. Maintaining the same or similar tension, bring the tubing 90 degrees to the left, and 90 degrees to the right. (Figure 6)

6.2.5.4. If the connector stays attached to the smoke evacuator, it is considered a Pass. If the connector does not stay attached, it is considered a Failure. Record results in the Pull Test column of the data sheet found in Appendix A.

6.2.6. Repeat steps 6.2.1. through 6.2.5. with the next filter or fluid trap, using a new ZIP PEN for each. Test all filters / fluid traps listed in Table 1 for part number 2155.

7. ACCEPTANCE CRITERIA

The connectors shall fit and remain securely attached to the compatible filters identified in Table 1 when the ZIP-PEN is extended to a tension indicative of reasonable use as described earlier in this protocol. The connectors shall pass both a visual fit test (see Figure 8) and a pull test to be deemed compatible with each filter.

Figure 8: Example of acceptable visual fit test for both C and EC connectors. Connectors should have minimal space between filter or fluid trap when fully inserted or attached. For secure attachment, fully seat the connector / tubing into the appropriate filter port.

8. APPENDIX A: DATA SHEET

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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#:	2150	CONSULT LOT HISTORY OF ZIP-PEN FOR CONNECTOR LOT #'S		S#: L#:			
2	L#:	2150			S#: L#:			
3	L#:	2150			S#: L#:			
4	L#:	2150			S#: L#:			
5	L#:	2150			S#: L#:			
6	L#:	2150			S#: L#:			
7	L#:	2150			S#: L#:			

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8	L#:	2150	CONSULT LOT HISTORY OF ZIP-PEN FOR CONNECTOR LOT #'S		S#: L#:			
9	L#:	2150			S#: L#:			
10	L#:	2150			S#: L#:			
11	L#:	2150			S#: L#:			
12	L#:	2155			S#: L#:			
13	L#:	2155			S#: L#:			
14	L#:	2155			S#: L#:			
15	L#:	2155			S#: L#:			
16	L#:	2155 (tubing only)		Stryker Neptune®	S#: L#:			

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Tested by:

Name:_____

Signature:_____ Date:_____