



# **Evaluation of Three New Fit Test Protocols for Use with the TSI PortaCount**

by

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## **Purpose:**

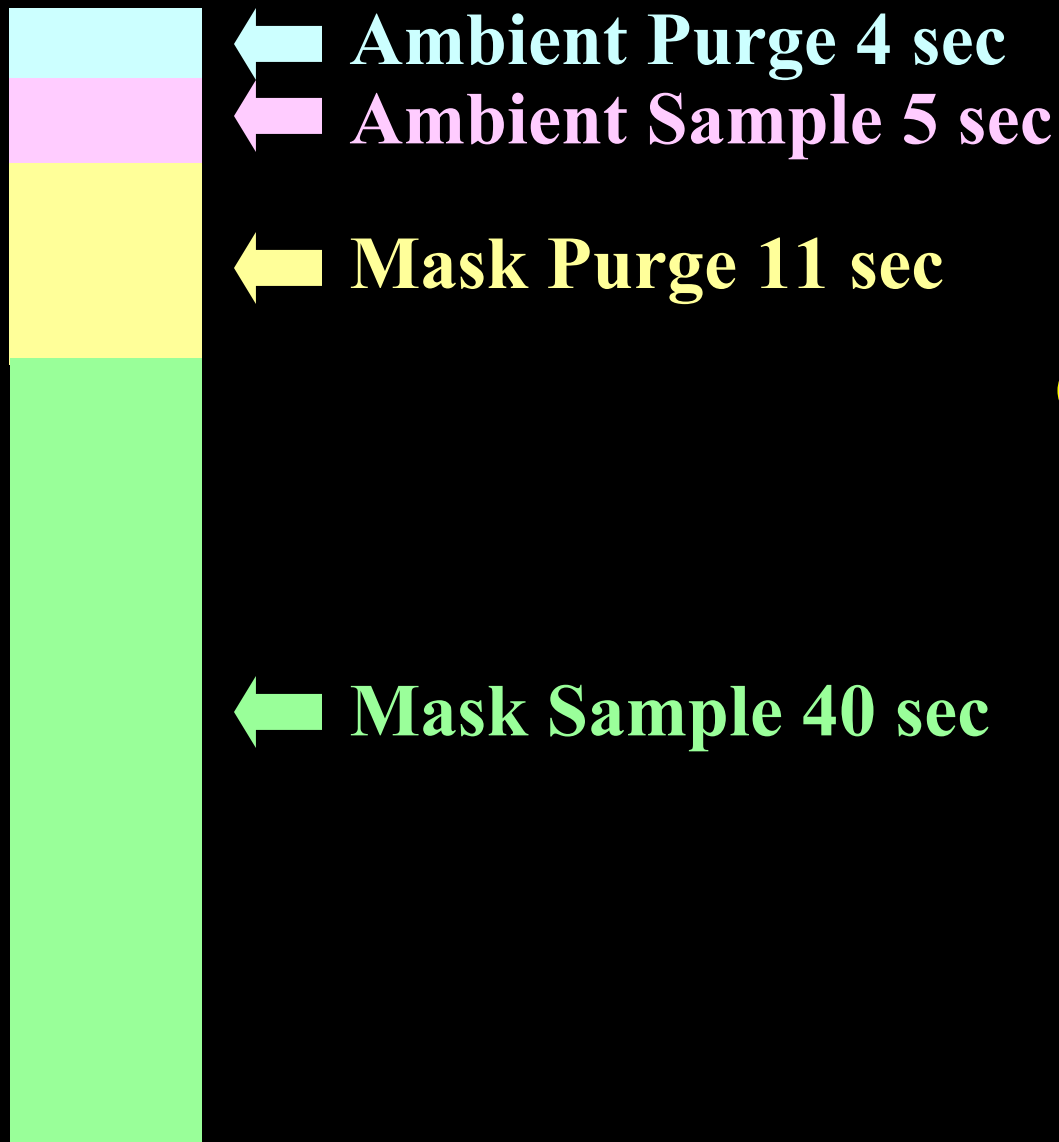
**To investigate three new fit testing protocols with shorter exercise times specifically designed for use with the TSI PortaCount.**

## **Methods:**

**Fit testing software was modified to permit data acquisition at ten (10) second intervals during mask sampling.**

**This allowed 10, 20, & 30-second fit factors to be compared to the OSHA 40-second fit factors as if they were different fit tests with identical donnings.**

# TSI PortaCount Plus Sampling Sequence

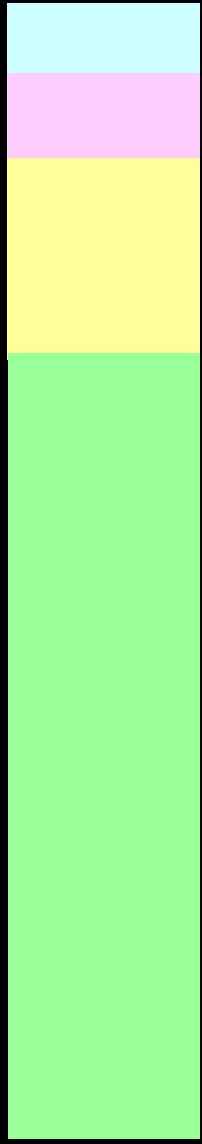


**OSHA Accepted  
Protocol**

# OSHA Protocol

# Protocol 1

# Protocol 2 & 3



← Ambient Purge 4 sec →

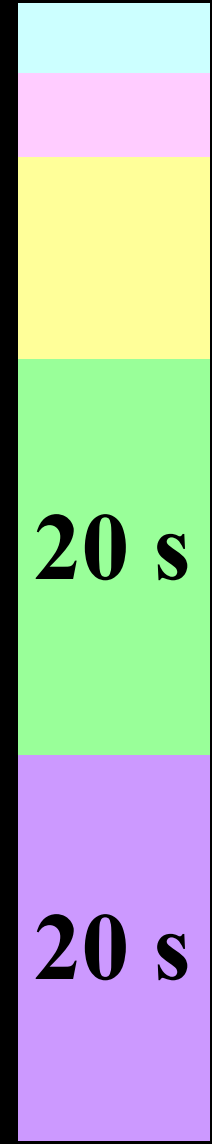
← Ambient Sample 5 sec →

← Mask Purge 11 sec →

Mask Sample → 10 s

← Mask Sample 40 sec →

Excluded → 30 s



20 s

20 s

## Advantages of this method:

- ❖ **Avoids problems associated with comparison studies using two different fit test methods. For example;**
  - ❖ **New method fit factors were compared to the reference method fit factors during the same donning.**
  - ❖ **Influence of previous exercise maneuvers was, therefore, eliminated.**
  - ❖ **Utilized same sample probe location, size, flow, etc.**

	<b>OSHA Protocol</b>	<b>Protocol #1</b>
<b>Pass levels (half/full)</b>	<b>100/500</b>	<b>100/500</b>
<b>Individual exercise time (seconds)*</b>	<b>60</b>	<b>30</b>
<b>In facepiece sampling time</b>	<b>40</b>	<b>10</b>
<b>Normal breathing</b>	<b>X</b>	<b>X</b>
<b>Deep breathing</b>	<b>X</b>	<b>X</b>
<b>Turn head side to side</b>	<b>X</b>	<b>X</b>
<b>Move head up and down</b>	<b>X</b>	<b>X</b>
<b>Talking</b>	<b>X</b>	<b>X</b>
<b>Grimace (15 seconds)</b>	<b>X</b>	<b>X</b>
<b>Bending over</b>	<b>X</b>	<b>X</b>
<b>Normal breathing</b>	<b>X</b>	<b>X</b>
<b>Total test time (minutes:seconds)</b>	<b>7:15</b>	<b>3:45</b>

**Protocol #3 eliminates the first two less challenging exercises, thus putting an emphasis on the more challenging exercises.**

# **Informed Consent & Medical Evaluation**



**Human subject approval was obtained from the University of Cincinnati's Institutional Review Board.**

**Medical clearance was obtained using an on-line web-based service available through the University of Cincinnati.**

## Results were compared to ANSI Z88.10-2001 Acceptance Criteria for Evaluating New Fit Test Methods

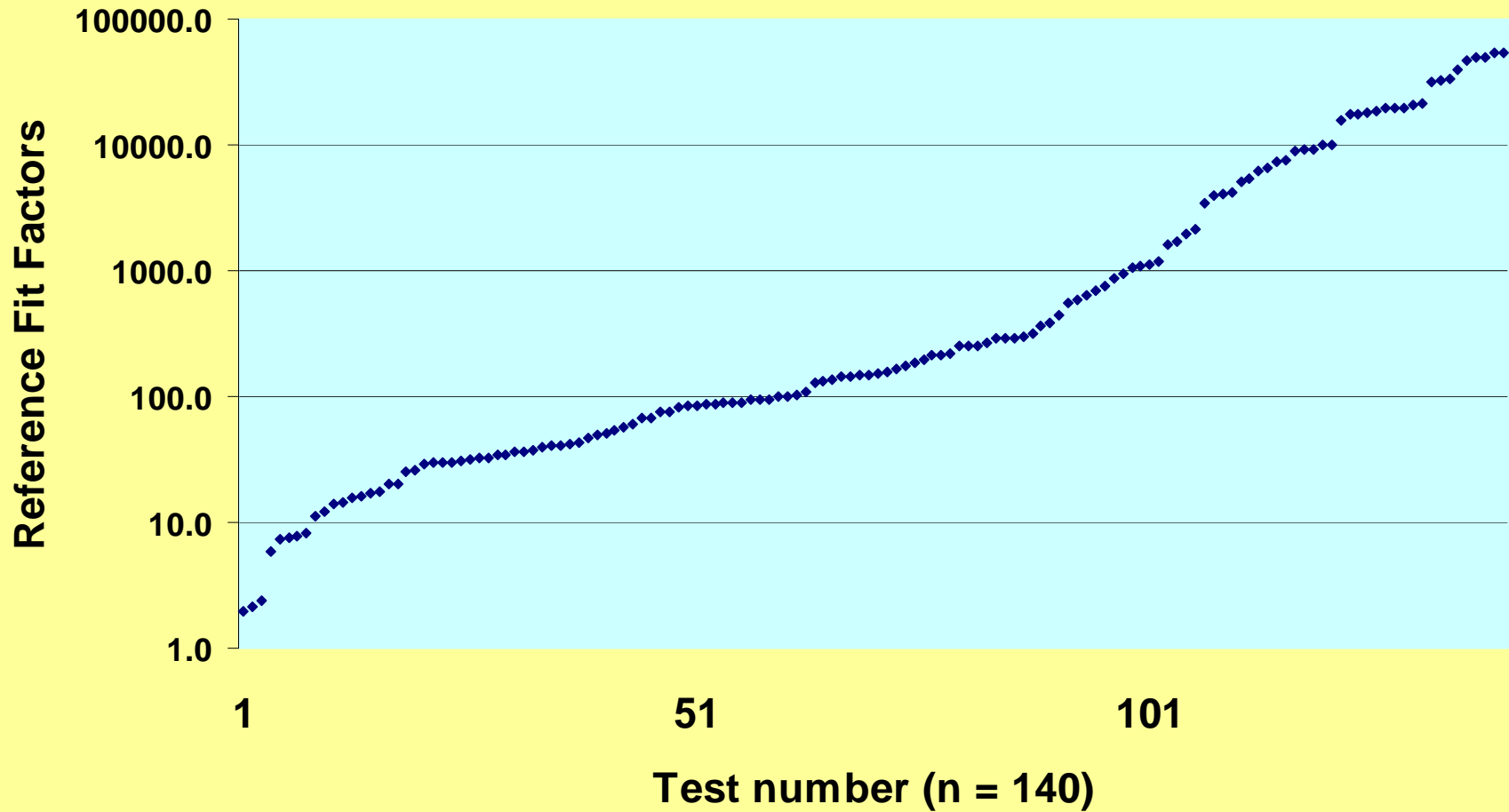
	ANSI Criterion	Study Results
<b>Minimum number of paired tests</b>	<b>100</b>	<b>140</b>
<b>Minimum number of test subjects</b>	<b>25</b>	<b>30</b>
<b>Minimum number of reference fit factors less than the required fit factor</b>	<b>50</b>	<b>57 &lt; fit factor of 100*</b> <b>91 &lt; fit factor of 500</b>
<b>Make and model facepieces</b>	<b>“Variety”</b>	<b>24</b>

\* After excluding 3 tests with reference fit factors within  $\pm 1$  SD (otherwise 60 reference fit factors were below 100).

# Number of Fit Tests

	Total Number of Fit Tests
<b>Half Masks</b>	<b>69</b>
<b>Full Face</b>	<b>71</b>
<b>All Masks</b>	<b>140</b>
<b>Reference Fit Factors &lt; 100</b>	<b>60</b>
<b>Reference Fit Factors &gt; 100</b>	<b>80</b>
<b>Reference Fit Factors &lt; 500</b>	<b>91</b>
<b>Reference Fit Factors &gt; 500</b>	<b>49</b>

## Distribution of Reference Fit Factors



# **Test Sensitivity**

**ANSI Z88.10 Sensitivity Requirement  $\geq 0.95$**

**Test sensitivity: The probability that the new fit test method will correctly identify an inadequately (ie., poorly) fitting respirator.**

**In essence, it answers the following question:**

**Of the reference method fit tests with unacceptable fits, what fraction also failed the new fit test method?**

**Answer should be  $\geq 95\%$ .**

**Sensitivity is sometimes called the  $\beta$  error.**

$$\text{Sensitivity} = \frac{C}{(A + C)}$$

**Reference Method**

		<b>Reference Method</b>	
		<b>Failed</b>	<b>Passed</b>
<b>New Method</b>	<b>Passed</b>	<b>A</b>	<b>B</b>
	<b>Failed</b>	<b>C</b>	<b>D</b>

**Since each fit testing protocol was compared to reference pass/fail criteria of 100 and 500, there are six (6) separate determinations made in this study**

<b>Protocol</b>	<b>Reference Pass/Fail Criterion</b>	<b>Exercise Time (sec)</b>	<b>Mask Sample Time</b>	<b>Sensitivity</b>	<b>Result</b>
<b>1</b>	<b>100</b>	<b>30</b>	<b>10</b>		
<b>2</b>	<b>100</b>	<b>40</b>	<b>20</b>		
<b>3</b>	<b>100</b>	<b>40</b>	<b>20</b>		
<b>1</b>	<b>500</b>	<b>30</b>	<b>10</b>		
<b>2</b>	<b>500</b>	<b>40</b>	<b>20</b>		
<b>3</b>	<b>500</b>	<b>40</b>	<b>20</b>		

**20 s Mask Sample**  
**40 s Exercise Time**  
**8 Exercises: Total Test Time = 4:55**  
**Pass Fail Criterion:**

**100 Reference Method**  
**100 New Method**

**Protocol #2**  
**Table IVb**

		Reference Method		
		Failed	Passed	
New Method Protocol #2	Passed	2	78	80
	Failed	55	0	55
		57	78	135

**Sensitivity = 0.97 Pass**

**20 s Mask Sample**  
**40 s Exercise Time**  
**8 Exercises: Total Test Time = 4:55**  
**Pass Fail Criterion:**  
**100 Reference Method**  
**100 New Method**

**Protocol #2**  
**Table IVb**

	<b>ANSI Requirement</b>	<b>Study Results</b>	<b>Pass or Fail</b>
<b>Sensitivity</b>	$\geq 0.95$	<b>0.97</b>	<b>Pass</b>
<b>Predictive Value of a Pass</b>	$\geq 0.95$	<b>0.98</b>	<b>Pass</b>
<b>Specificity</b>	$> 0.50$	<b>1.00</b>	<b>Pass</b>
<b>Predictive Value of a Fail</b>	$> 0.50$	<b>1.00</b>	<b>Pass</b>
<b>Kappa Statistic</b>	$> 0.70$	<b>0.97</b>	<b>Pass</b>

**20 s Mask Sample**  
**40 s Exercise Time**  
**6 Exercises: Total Test Time = 3:35**  
**Pass Fail Criterion:**  
**100 Reference Method**  
**200 New Method**

**Protocol #3**  
**Table IVc:**

		Reference Method		
		Failed	Passed	
New Method Protocol #3	Passed	0	63	63
	Failed	57	15	72
		57	78	135

**Sensitivity = 1.00 Pass**

**20 s Mask Sample**  
**40 s Exercise Time**  
**6 Exercises: Total Test Time = 3:35**  
**Pass Fail Criterion:**  
**100 Reference Method**  
**200 New Method**

**Protocol #3**  
**Table IVc:**

	<b>ANSI Requirement</b>	<b>Study Results</b>	<b>Pass or Fail</b>
<b>Sensitivity</b>	$\geq 0.95$	<b>1.00</b>	<b>Pass</b>
<b>Predictive Value of a Pass</b>	$\geq 0.95$	<b>1.00</b>	<b>Pass</b>
<b>Specificity</b>	$> 0.50$	<b>0.81</b>	<b>Pass</b>
<b>Predictive Value of a Fail</b>	$> 0.50$	<b>0.79</b>	<b>Pass</b>
<b>Kappa Statistic</b>	$> 0.70$	<b>0.78</b>	<b>Pass</b>

**20 s Mask Sample**  
**40 s Exercise Time**  
**6 Exercises: Total Test Time = 3:35**  
**Pass Fail Criterion:**  
**500 Reference Method**  
**1000 New Method**

**Protocol #3**  
**Table Vc:**

		Reference Method		
		Failed	Passed	
New Method Protocol #3	Passed	0	41	41
	Failed	91	8	99
		91	49	140

**Sensitivity = 1.00 Pass**

**20 s Mask Sample**  
**40 s Exercise Time**  
**6 Exercises: Total Test Time = 3:35**  
**Pass Fail Criterion:**  
**500 Reference Method**  
**1000 New Method**

**Protocol #3**  
**Table Vc:**

	<b>ANSI Requirement</b>	<b>Study Results</b>	<b>Pass or Fail</b>
<b>Sensitivity</b>	$\geq 0.95$	<b>1.00</b>	<b>Pass</b>
<b>Predictive Value of a Pass</b>	$\geq 0.95$	<b>1.00</b>	<b>Pass</b>
<b>Specificity</b>	$> 0.50$	<b>0.84</b>	<b>Pass</b>
<b>Predictive Value of a Fail</b>	$> 0.50$	<b>0.92</b>	<b>Pass</b>
<b>Kappa Statistic</b>	$> 0.70$	<b>0.87</b>	<b>Pass</b>

# Summary of Test Sensitivity

## ANSI Z88.10 Sensitivity Requirement $\geq 0.95$

Protocol	Reference Pass/Fail Criterion	Exercise Time (sec)	Mask Sample Time	Sensitivity	Result
1	100	30	10	0.91	Fail
2	100	40	20	0.97	Pass
3	100	40	20	1.00	Pass

**All three protocols were highly correlated  
with the reference fit test method**

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<b>Protocol Number</b>	<b>Correlation Coefficient</b>
<b>1</b>	<b>0.956</b>
<b>2</b>	<b>0.988</b>
<b>3</b>	<b>0.982</b>

# Conclusions



**Reducing exercise time with the TSI PortaCount using these three protocols had little effect on the ability of this instrumentation to identify poorly fitting respirators.**

**Protocol #2 exceeded all ANSI criteria.**

**This protocol has a shorter mask sampling time (20 versus 40 seconds), with the same number of exercises.**

# Conclusions



**If you're a little uncomfortable with the shorter mask sampling time, you may want to consider protocol #3.**

**Protocol #3 has the same mask sampling time as protocol #2, but eliminates the first two (less challenging) exercises from the OSHA protocol. In addition, it requires doubling the pass/fail criterion.**

**This not only provides a significantly faster fit test protocol, but also provides a more conservative fit test.**

## **Acknowledgements:**

**This study was supported in part by TSI Inc., Shoreview, MN, USA.**

**The authors exercised full control over the design and execution of the study as well as the interpretation and reporting of results.**



**For additional  
information, go to:**

**McKay RT, Bradley J.**

**Evaluation of Three New Fit Test Protocols for  
Use with the TSI PortaCount.**

***Journal of the International Society of  
Respiratory Protection***

**22:112-121, 2005.**

**or, e-mail [Roy@DrMcKay.com](mailto:Roy@DrMcKay.com)**



# Questions?

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