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Fit-Checking v Fit Testing for FFP

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Aim and Objectives

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Aim:

- Investigate the reliability of using simple subjective methods to assess fit of FFP3

Objectives:

- Analyse the results of fit-checks, using the ANSI/AIHA Z88.10-2010 criteria for acceptance of new fit test methods
- Consider also the wearer subjective opinion and fit tester subjective opinion

Methodology

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- FFP3 fit test review study
- Study design followed ANSI/AIHA Z88.10-2010 requirements
- FFP3 donned
- Fit-checked by wearer
- Subjective assessment carried out
  - Wearer
  - Fit tester
- Test run of 4 different fit tests
- Subjective assessment of fit
  - Wearer
  - Fit tester

Test runs

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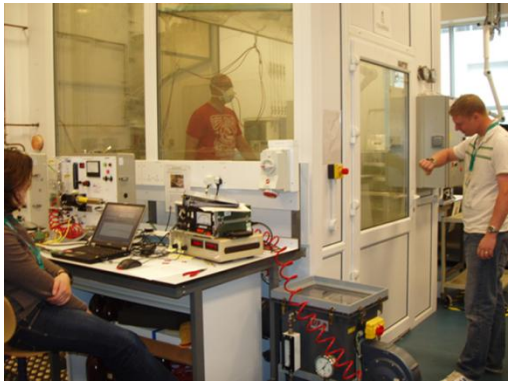
- For each test run the volunteer test subject wore an FFP3 for about 1 hour, without disturbing the fit
- FFP3 selection randomised
  - Different mask model each time for each test subject
- 4 different fit tests carried out
  - Random order
- HSE guidance 282/28 protocol followed
  - Exercises
  - Measurement time

Methodology



- 4 Fit tests
  - Bitrex qualitative
  - Portacount
  - Portacount with N95 companion
  - Test chamber EN 149 TIL test
- 25 test subjects
- 9 different FFP3 models
  - Wide range of design features
    - Fold flat vertical/horizontal
    - Cup shaped rigid/soft
    - Noseshape fixed/adjustable with clip
    - Face seal elastomeric/filtering material/knitted fabric
    - Fixed/adjustable length straps

Fit-checks and subjective assessments

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- Fit-check - loosely cover filtering material with hands and breathe in sharply
- Subjective assessment
  - Wearer moved head to allow fit tester to inspect for gaps
  - side to side
  - up and down
- Subjective opinions recorded
  - fit tester
  - wearer

Results of fit-checks

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Fit-check	
pass	106
unsure	8
fail	16
total	130

ANSI calculations reference fit test TIL

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ANSI/AIHA Z88.10-2010 Annex A2 analysis calculations									
Pass criteria		all 100		Test sensitivity required >/=0.95	Beta error required =/<0.05	Predictive value of pass suggested >/=0.95	Test specificity suggested >0.5	Predictive value of a fail suggested >0.5	Kappa Statistic recommended >0.7
		TIL Failed	TIL passed						
	Passed	A	B						
Formulae	failed	C	D	C/(A+C)	1-(C/(A+C))	B/(A+B)	B/(B+D)	C/(C+D)	
		TIL Failed	TIL passed						
Bitrex	Passed	9	24						
Bitrex	failed	65	19	0.88	0.12	0.73	**0.56**	**0.77**	**0.46**
		TIL Failed	TIL passed						
Portacount	Passed	1	18						
Portacount	failed	73	25	**0.99**	**0.01**	**0.95**	0.42	**0.74**	**0.46**
		TIL Failed	TIL passed						
Portac. +N95	Passed	5	25						
Portac. +N95	failed	69	18	0.93	0.07	0.83	**0.58**	**0.79**	**0.55**
		TIL Failed	TIL passed						
fit-check	Passed	61	35						
fit-check	failed	13	8	0.18	0.82	0.36	0.81	0.62	-0.01

Similar test sensitivities found by *Lam et al; (2011) Sensitivity and specificity of the user -seal -check in determining the fit of N95 respirators; Journal of Hospital Infection Vol 77, Issue 3, March 2011, pages 252-256 Proceedings from the Sporicidal Workshop*

Fit-check result ordered by TIL fit factor

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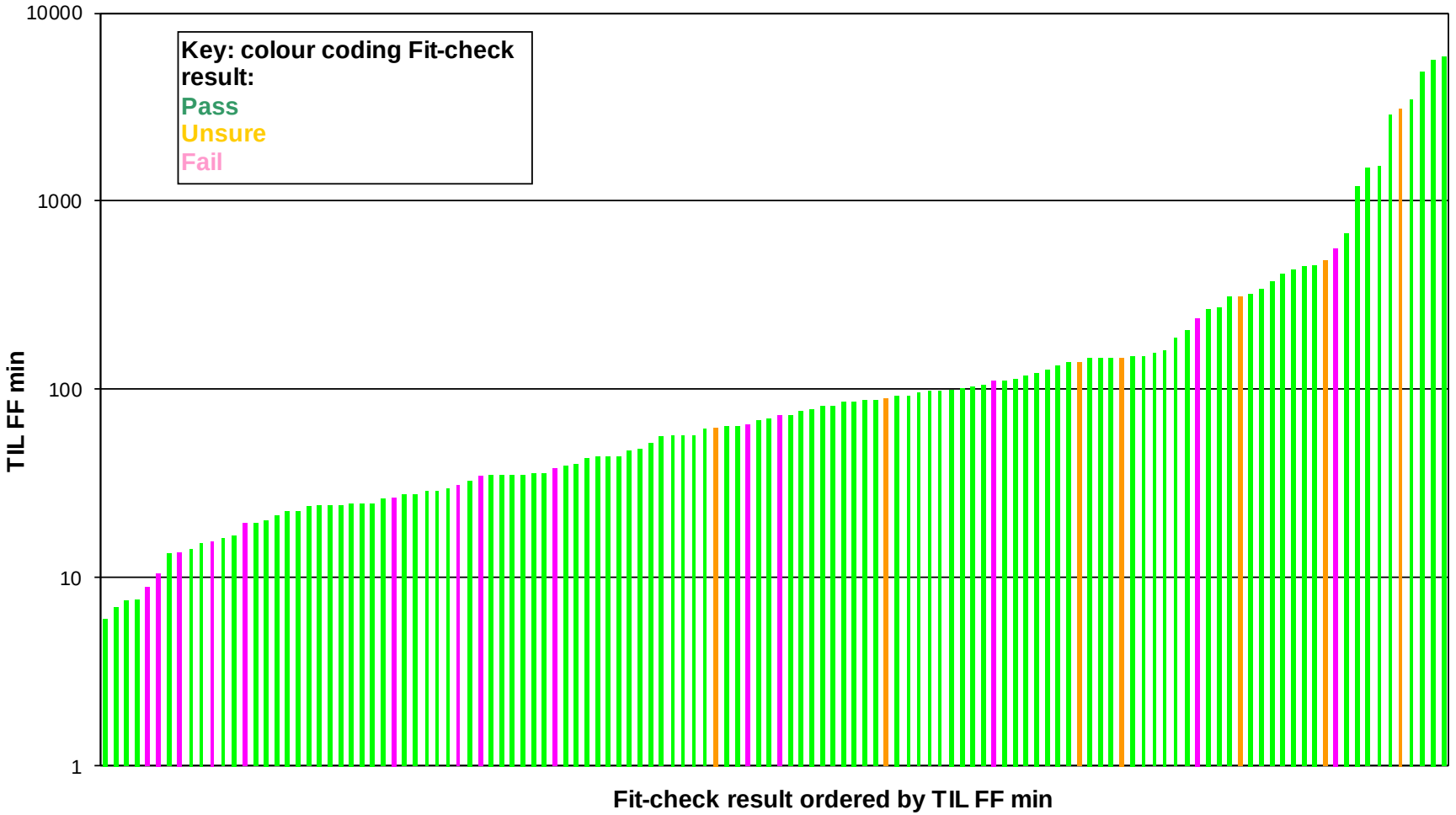

Subjective assessments

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- 61 test runs failed in all 4 fit test methods
- Of these ‘confirmed poor fits’ subjective assessment results were assessed
  - fit-check
  - wearer/test subject pre test run
  - wearer/test subject post test run
  - fit tester pre test run
  - fit tester post test run

Subjective assessment

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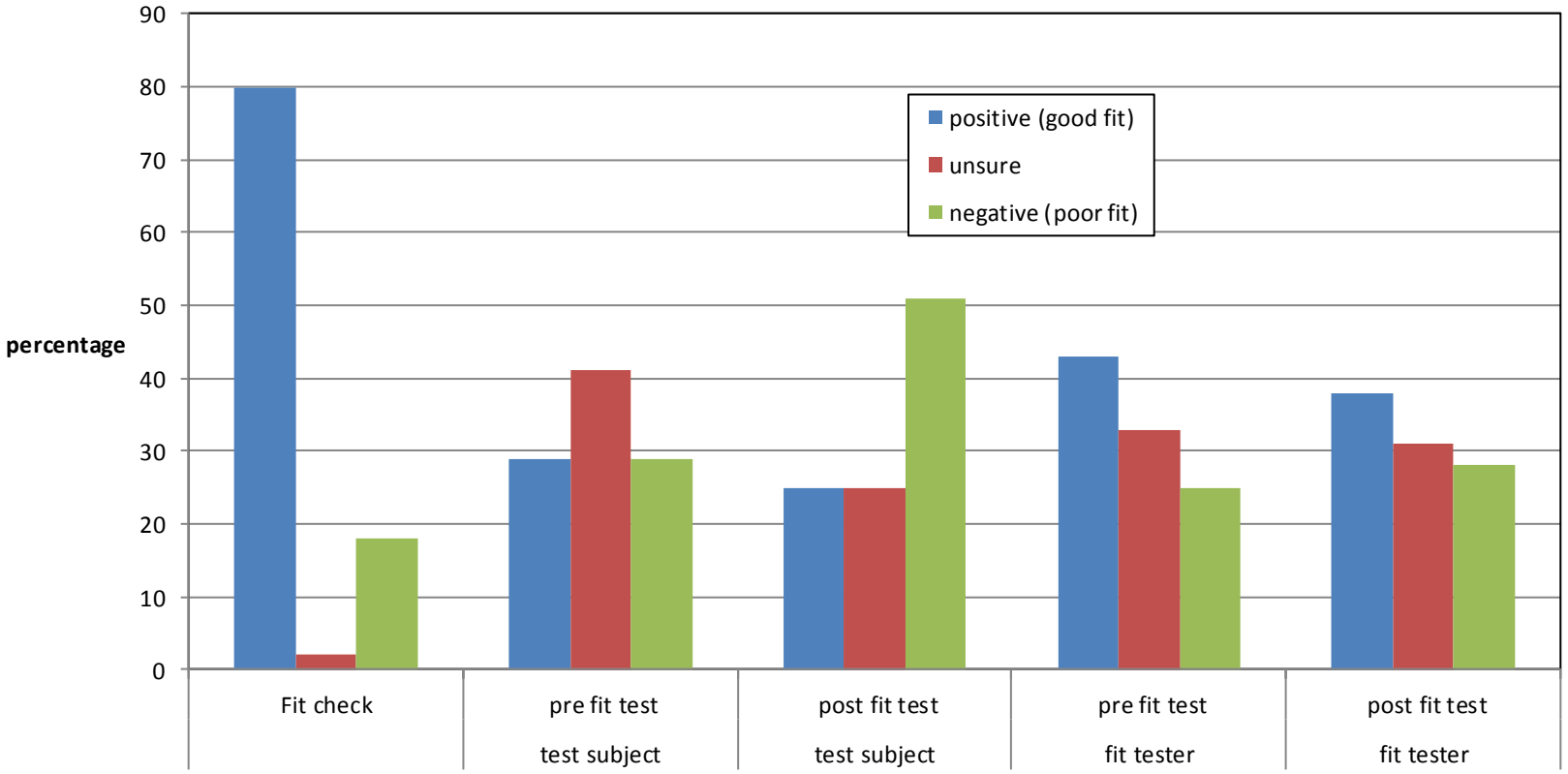

Wearer pre test run comments

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- Negative
  - “wouldn’t want to wear for real. Some movement on nose when talking, smiling”;
  - “A bit insecure under chin but otherwise OK. Feels as if may shift around a bit”.
- Positive
  - “feels comfortable, straps easy, donning easy, right size”;
  - “feels comfortable and leaktight”.

Wearer post test run comments

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- Positive
  - “feels fine no leaks felt, comfortable on nose”;
  - “good - best so far”.

Fit tester comments

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- Pre test run
  - “wide fabric seal appears to be in good contact all around”;
  - “looks OK. nose clip well shaped, chin snug”.
- Post test run
  - “OK no gaps. Face marked”;
  - “Nose seal appears to fit and mask appears snug under chin”.

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Thank you for your attention

Questions?