PAPR USE in HEALTHCARE

Institute of Medicine’s Public Workshop on Powered Air-Purifying Respirators (PAPRs)
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Larry Green
Syntech, Intl
Historical Overview - SHS in Healthcare
(Surgical Helmet Systems)

- **Same components as a PAPR.**
  - Intake air filters, Blower, Battery, Lens, body coverings

- **> 25 years of in Healthcare**
  - 25 years of development evolution focused on Healthcare needs
  - Current: > 10K uses/week

- **FDA approved**
  - Device codes: FYA, FXY  Standard: ASTM F2407

- **Not NIOSH approved**
  - Filtration < respirator requirements
Historical Overview - SHS in Healthcare
(Surgical Helmet Systems)

- MAXAIR doubles as NIOSH Respirator and FDA SHS
  - Quick and easy donning
  - High airflow levels
    provide cooling to surgical suits
  - User adjustable airflow
  - Efficient CO₂, heat and moisture exchange
    Enhanced by breathable filtering hoods
  - Micro porous viral barrier materials
    improve moisture and heat exchange for body coverings.
  - Quieter fans
    with low resistance TH1/TH2 or hygienic (BFE rated) filters
  - Minimized cleaning
    with fully covered blowers.
Healthcare Needs

Efficacy

Comfort

Ease of Use
Healthcare Needs

• Ease of Use
  – No Fit Testing
  – Donning and Doffing
  – Cleaning
  – Operational Time
  – Always visible battery meter and airflow alarm
Historical Overview - SHS in Healthcare
(Surgical Helmet Systems)

Similarities:
SHS & PAPR
– Donning SHS Hood
Similar Donning, Easy Attachments
SHS Togas or PAPR isolation gowns offer unbroken Head down protection
Remove from hook, place on head, seal check, headband adjustment, DONE

Automatic Power ON
MAXAIR Helmet Battery

• >10 second donning for emergencies and routing care
• Recharge Cradle
• Fast recharge Li-Ion batteries

• Battery level meter always visible
• Port for attaching larger battery if required
  – Helmet stays running if added while in use.
Advantages of Shorter Life Batteries

• **Weight**
  – Lighter is preferred
  – 8-10 hr Batteries can be placed in the pocket
  – Helmet battery feasible.

• **Faster donning**

• **A16-20 hour battery is available.**
Healthcare Needs

• Comfort
  – CO₂ levels
  – Temperature/Cooling
  – Noise
  – Visibility
  – Weight
PAPR Comfort

• Almost no breathing resistance.

• Cooling airflow
  • over the face and into over-garments depending on the configuration.

• Low levels of retained CO$_2$.

• Newer are much quieter

• High peripheral view area
Optimal Flow Rates for HC Workers

• Flow Rate
  – Maintain Positive Pressure
    • NIOSH has reference values for Low, Medium and High work rates
    • Means to measure and control pressure in PAPRs exist
    • Full hoods provide a large reserve
  – Purges CO$_2$
  – Provides cooling
  – Excess can cause discomfort
  – Active Pressure monitoring and control almost eliminates the possibility of over-breathing.
• CO₂ Levels
  – Elevated levels cause Hypercapnia
    • There are sufficient sources for physiological effects of Hypercapnia.
    • Some early effects; Drowsiness, Headache, Increased Heart Rate*
  – The symptoms of Claustrophobia** are similar to the symptoms of Hypercapnia
  – User discomfort

*http://en.wikipedia.org/wiki/Hypercapnia
**http://www.medicalnewstoday.com/articles/37062.php
• NIOSH & CE: <10,000 ppm (machine)
• What level of CO₂ is optimal for respirators used in Healthcare?
  – Do the very early effects of hypercapnia interfere with responsibilities?
  – Do the very early effects of hypercapnia interfere with the willingness of the personnel to use the respirator?
  – What levels of CO₂ cause user discomfort?
• In the early 1990s the target for SHS was 5000 ppm. (human subject)
  – This was a marketing tool which required very breathable hood materials to reach.
  – Above 5000 ppm discomfort was greater
  – Below 3000 ppm discomfort was minimal
Temperature & Cooling

• Heat build up in full body PPR is a Major health concern.
  – Dehydration and hyperthermia can greatly restrict use times.

• PAPRs cool the face.

• PAPRs cool the body.
  – With a full hood, the air continues into the over garment
  – Coverall type over garments will inflate as the positive pressure field is extended into them
  – Togas (open at bottom) vent the air out the bottom with minimal inflation

• An excess of air across the face can cause discomfort for sedentary (desk) workers.
Temperature control features

• Flow rate
  – Higher flows for more active workers (250+ lpm)
• Toga type garments offer less restricted cooling air flow over the body
  – Fully integrated head and body protection
  – Vent out the bottom
• High breathability filtering hood materials minimize heat build up around the head.
• Micro-porous viral barrier materials offer improved venting of heat and moisture.
• Secondary body cooling devices are available.
Noise

• Noise
  – MAXAIR (current) 55-70 dBA
  – Stryker Flyte SHS 51- 62 dBA
  – Newer Traditional ~ 60 dBA
  – Older Traditional 70+ dBA
  – Older SHS 70+ dBA

• Improvements in Blower (fan) design
• Improvements in Filter design
• Improvements in Airflow Control

• MAXAIRs current best in R&D ...... 52 dBA
Healthcare Needs

• Efficacy
  – Patient communication
  – Hygienic Protection, fluid resistance
  – Respiratory Protection
Communication

• Detriments
  • Noise
  • Face Shield
    – Sound reflects off the plastic
    – Some users report that people standing behind the wearer can hear them better.

• How does the sound reflection compare to the muffling effect of an FFP?
• How well do regular users learn to compensate (speak louder)?
• Is full face visibility of great enough importance to require the users to speak more clearly?
• Is full face visibility an advantage over the hidden mouth and nose with an FFP?
• Does the feel of a FFP remind a wearer to speak more clearly?
• The military uses mechanical sound transducers in some of their respirators.
• Some amplifier options have been explored for Surgical Helmet Systems.
• There are other options which are being explored.
Visibility

- MAXAIR has **>95% field of vision (CE)**, near optical clarity.
- Newer PAPRs are similar.
- Surgical Helmets Systems are similar.
- Newer PAPRs advertise improved window shape to reduce glare.
- Anti-glare coatings are available for significant added cost.
- Lower quality lens materials are available for significantly reduced cost.
AAMI/ANSI PB70 Fluid Barrier Levels

- **Level 1**
  - <4.5g Impact Penetration (H₂O)

- **Level 2**
  - <1.0g Impact Penetration (H₂O)
  - >25 cm Hydrostatic Head (H₂O)

- **Level 3**
  - < 1.0g Impact Penetration (H₂O)
  - > 50cm Hydrostatic Head (H₂O)

- **Level 4**
  - Pass ASTM F1671 (live) Viral Penet Test (low surface tension)
  - Screen with ASTM F1670 Synth Blood Test (low surface tension)

- Is a live virus test necessary to certify an isolation gown?
- Can a modified synthetic Blood be more sensitive than a live viral test?
• There are multiple filter & protection options
  - SHS BFE rated filters 99+% (>1μ)
  - CE TH1 filters 92% (0.6μ mean)
  - CE TH2 filters 98% (0.6μ mean)
  - CE TH3 filters 99.8 (0.6μ mean)
  - PAPR95 (NIOSH proposed) 95% (0.3μ mean)
  - HE (NIOSH) filters 99.97% (0.3μ mean)
  - APF 1000 filters (OSHA) >99.99% (@MPPS ~ 0.05μ)

• CE also has both oil resistant and non-oily classifications.

• MAXAIR w/ TH1/TH2 filter  55 dBA
• MAXAIR @ 170 lpm w/HE  52 dBA
• 55 dBA is 1/100 the sound energy of 75 dBA

* some products are in development
PAPR Efficacy

• NO FIT TESTING

• NO GAPS in protection
  • Because loose fitting PAPRs are a PPE System

• COMPATIBLE with standard eye-wear, facial hair, all facial features.

• FULL Head and body hygienic protection.
  • Viral Barrier garments with welded seams

• Cooling for Hyperthermia Protection

• Greater Protection Factors are available
Pandemic Preparedness

• EFFICACY is the biggest part of PP.
• High Flow rates for Hyperthermia Protection
• Cleanable garments
  • MAXAIR CAPR shrouds and cuffs can be rinsed in a disinfecting solution if necessary.
  • Replacement DLC lens/cuffs are less expensive and more compactly packaged then traditional cuffs
• Completely covered blowers and batteries minimize cleaning
  • Traditional PARPs are cumbersome to effectively disinfect.
How do I avoid stale inventory?

• MAXAIR Surgical Helmet System hoods and togas are able to be used with existing Post filter cartridges to meet HE or greater filtration requirements.

• MAXAIR Surgical PAPR components will be ready to go.
  – Provides a potentially large local inventory of regularly used products to be re-tasked.
  – Regularly used products allow large production capacity to be maintained.
  – Regularly used products allow large regionally warehoused stocks to be maintained.
  – FIFO minimizes out of date product.
Contaminated Doffing?

Turn it inside out.
Improve effective use of PAPRs in Healthcare

** Loose Fitting PAPRs are a PPE System **

• Describe required PPE using “with”, not “and”
  – I need a respirator with facial protection.
  – I need a respirator with full body protection.
  – PPE should always work with all is parts.

• Describe PPE in terms of protection.
  – I need an APF 25 respirator with AAMI Level 4 barrier protection
  – I need an APF 100 respirator with high airflow for hyperthermia protection

• Request what you need to, not THINK will, work together.
Top 4 Regulatory Issues

• Silica Dust Testing
  • Allow LRPL testing, active airflow alarms and battery level alarms be considered equivalent to silica dust testing for non-loading or healthcare environments under the current 42 CFR part 84.

• Allow NaCl testing as an alternative to DOP and Corn oil testing
  • DOP is incompatible with the bio-compatibility testing required for surgical garments.
  • NaCl can be used both for filter and TIL testing

• Look at Loose Fitting PAPR certification as a PPE system.

• FDA 3rd party evaluation and consensus standards guidance be should be able to be used to create a unified certification process.
Top 3 standards issues

- Any new standard should be written to allow new information or technology to be more easily adopted.
  - Creating completely separate respirator standard and certification program for healthcare would be VERY undesirable.
- What are the appropriate TIL protection factors for PAPRs in healthcare?
- Testing standards should be designed to be workable in production environments not laboratories.
  - Look at options to ASTM F1671 for level 4 gowns.
  - Avoid BFE testing requirements for filters
Differences: Healthcare vs Industrial

• Primary hazards; virus and bacterial; generally not TWA or PEL dependent
• Contaminants can increase from point of exposure
• Most/all emergencies are not escape situations
  – e.g. Donning speed can be life threatening to other than the PPE user
• Body fluids: blood, gastric juices, etc
• Mostly short duration activities – 5-25 min.
• Generally “clean air” – minimal filter clogging particulates
Larry Green
Syntech, Intl
www.maxair-systems.com