

# Check the Label: Is the Mask a Level 1, 2, or 3?

(... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)



## CHECK THE LABEL:

***Is the Mask a Level 1, 2, or 3  
and ... what's the difference?***

Kathy Stoessel, MS, BSN, RN  
Senior Manager, Clinical Education  
Kimberly-Clark Health Care



***Check the Label: Is the Mask a Level 1, 2, or 3?  
(and ... what's the difference?)***

### Objectives

- Identify three reasons for face mask use in healthcare
- Discuss the roles of the FDA and ASTM as relates to medical face masks
- Recognize requirements for the new ASTM F2100-11 mask performance rating
- Describe how the ASTM F2100-11 rating can assist with mask selection

## Face Masks in Healthcare Settings



### Three purposes:

- ➡ Worn by healthcare personnel to **protect them** from contact with infectious splashes and sprays

Check the Label: Is the Mask a Level 1, 2, or 3?  
(... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

## Face Masks in Healthcare Settings

### Three purposes:



- Worn by healthcare personnel to **protect** them from contact with infectious splashes and sprays
- Worn by healthcare personnel to **protect patients** from exposure to infectious agents carried in a healthcare worker's mouth or nose

Siegel JD, et al. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings.

## Face Masks in Healthcare Settings

### Three purposes:



- Worn by healthcare personnel to **protect** them from contact with infectious splashes and sprays
- Worn by healthcare personnel to **protect patients** from exposure to infectious agents carried in a healthcare worker's mouth or nose
- Worn by patients to limit potential dissemination of infectious respiratory secretions from the patient to others (**protect others**)

Siegel JD, et al. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings.

## Face Masks in Healthcare Settings

A mask may be used in combination with goggles or a face shield to protect the mouth, nose and eyes



Siegel JD, et al. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings.

# Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

## Face Masks in Healthcare Settings

- Are loose-fitting and disposable
- Differ in *design, breathability, fluid protection, large-particle droplet protection*
- May be labeled as surgical, isolation, dental or medical procedure masks
- May utilize ties, ear loops or over-the-head bands as fasteners



Institute of Medicine. Reusability of Facemasks During An Influenza Pandemic: Facing the Flu: The National Academies Press; 2006.  
Brosseau LM. Surgical Mask Performance. PPE for Healthcare Workers Against H1N1 Influenza A: IOM Workshop; 2009.  
Center for Devices and Radiological Health. Surgical Masks - Premarket notification [510(k)] submissions 2004.

## Which Mask Should You Choose?



## Which Mask Should You Choose?



- Assess:
  - breathability
  - ease of removal without self-contamination
- Ensure the mask provides:
  - good face coverage and fit
  - compatibility with eye wear
  - adequate bacterial filtration and fluid resistance given the risk of exposure

**Understand and use FDA and ASTM criteria for Medical Face Masks**

Siegel JD, et al. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings.

## Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellenia – ASC focus)

## ■ What roles do the FDA and ASTM play?



FDA: Food and Drug Administration

## The Food and Drug Administration (FDA):

- oversees the sale and marketing of surgical masks



Oberg T, Brosseau LM. Surgical mask filter and fit performance. *Am J Infect Control*. May 2008;36(4):276-282.

## What is a surgical mask?

According to the FDA:

A surgical mask:

1. must meet FDA criteria
2. may be labeled as:
  - surgical,
  - laser,
  - isolation,
  - dental, or
  - medical procedure m



# Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

## The Food and Drug Administration (FDA):

- oversees the sale and marketing of surgical masks
- recommends that manufacturers demonstrate mask performance in 4 areas:
  - fluid resistance
  - differential pressure
  - filter efficiency
  - flammability



Oberg T, Brousseau LM. Surgical mask filter and fit performance. *Am. J. Infect. Control.* May 2008;36(4):276-282.

## The Food and Drug Administration (FDA):

- oversees the sale and marketing of surgical masks
- recommends that manufacturers demonstrate mask performance in 4 areas:
  - fluid resistance
  - differential pressure
  - filter efficiency
  - flammability



### The FDA recognizes ASTM International test standards

Oberg T, Brousseau LM. Surgical mask filter and fit performance. *Am. J. Infect. Control.* May 2008;36(4):276-282.

## ASTM International

- ASTM International is one of the world's largest standards developing organizations



## ASTM International

- ASTM International is one of the world's largest standards developing organizations
- ASTM standards are voluntary and are used globally in:
  - **research and development**
  - **quality systems**
  - **commercial transactions**
  - **product testing and acceptance**



## ASTM International

- ASTM International is one of the world's largest standards developing organizations
- ASTM standards are voluntary and are used globally in:
  - **research and development**
  - **quality systems**
  - **commercial transactions**
  - **product testing and acceptance**



## ASTM F2100:

Standard Specification for  
Performance of Materials Used in Medical Face Masks

- This standard specifies test results required for labeling mask levels of barrier performance
- Tests performed:
  - fluid resistance
  - differential pressure (breathability)
  - bacterial filtration efficiency
  - particulate filtration efficiency
  - flame spread

## Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

**ASTM F2100:**  
Standard Specification for  
Performance of Materials Used in Medical Face Masks

Medical Face Mask Material Requirements			
Characteristic	Test	Test Standard	Test Standard Reference
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	ASTM Standard: F1862		
Differential pressure, mm H2O/cm2	Military Standard: MIL-M-36954C		
Bacterial filtration efficiency (BFE) (3 micron aerosol of staph aureus)	ASTM Standard: F2101		
Sub-micron particulate filtration efficiency (PFE) at 0.1 micron	ASTM Standard: F2299		
Flame spread	Federal Standard: 16 CFR Part 1610		

## Why do you need a fluid resistant mask?

## Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)



*Fluids potentially infected with bloodborne pathogens include:*

- blood
- semen
- vaginal secretions
- cerebrospinal fluid
- synovial fluid and peritoneal fluid
- amniotic fluid
- saliva in dental procedures
- any body fluid that is visibly contaminated with blood, and ... *all body fluids in situations where it is difficult or impossible to differentiate between body fluids*



## *Examples of increased risk of splash, spray, amount of fluid/blood contamination*

- Use of “splatter” instruments (e.g., high-speed hand pieces, saws, burs)
- Irrigating wounds and/or suctioning
- Arterial spouts

“Splatter” instruments and air-water syringes create a visible spray that contains droplets of water, saliva, blood, microorganisms, and other debris which can land on the healthcare worker, nearby surfaces or the patient.



### *Examples of increased risk of splash, spray, amount of fluid/blood contamination*



VELOCITY  
VOLUME }  exposure risk to  
bloodborne pathogens

Check the Label: Is the Mask a Level 1, 2, or 3?  
(... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

## Resistance to Penetration by Synthetic Blood **ASTM F1862**

What is Differential Pressure ( $\Delta P$ ) and why is it important?

$\Delta P$  measures the effort it takes to force air through the mask material

The lower the  $\Delta P$ , the more breathable and comfortable the mask



## Differential Pressure Test

MIL-M-36954 C: ΔP

### Comfort Scale used in Delta-P testing

Score	Perception
Above 5.0	hot
4.0 to 5.0	very warm
3.0 to 4.0	warm
2.0 to 3.0	cool
1.0 to 2.0	very cool



March 21, 2012 Webinar (Excellentia – ASC focus)

### What are the BFE, PFE – Why are they important?

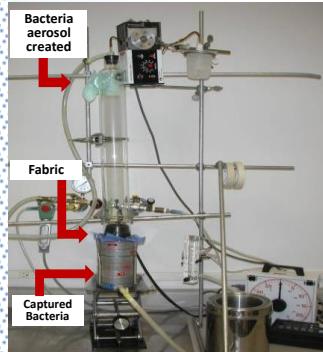
**BFE and PFE** describe mask performance for bacteria filtration efficiency (BFE) and particle filtration efficiency (PFE)

The higher the percentage, the more the mask prevents the passage of bacteria or particles



### Bacterial Filtration Efficiency (BFE)

*ASTM F2101*



Challenge bacteria:  
3 micron aerosol of  
*Staphylococcus aureus*

### How Small is a Micron?

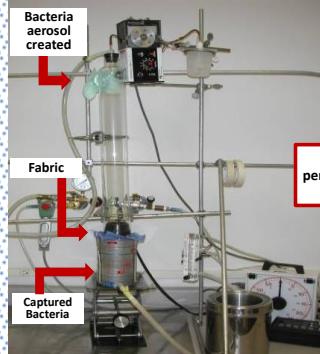
Particle	Particle Size (in microns or $\mu\text{m}$ )
One Inch	25,400
Dot (.)	615
Textile Fibers	10 – 1,000
Red Blood Cells	5 – 10
Mycobacterium tuberculosis	2-4 in length; 0.2-0.5 in width
<i>Staphylococcus aureus</i> bacteria	0.8 – 1.0
<i>Streptococcus pneumoniae</i> bacteria	0.9
Rhinovirus - virus	0.023

Adapted from The Engineering ToolBox [http://www.engineeringtoolbox.com/particle-sizes-d\\_934.html](http://www.engineeringtoolbox.com/particle-sizes-d_934.html) Accessed 3.8.11, and  
Clean Air Solutions <http://www.camfilfarr.com> Accessed 7.8.11

March 21, 2012 Webinar (Excellentia – ASC focus)

## Bacterial Filtration Efficiency (BFE)

ASTM F2101



Challenge bacteria:  
3 micron aerosol of  
*Staphylococcus aureus*

Results are expressed in  
percentage (%) that does NOT pass through  
the fabric at a given aerosol flow rate

## As an example...

If barrier fabric is challenged with 2,200\* bacteria:

% Filtration Efficiency	# Bacteria pass through fabric
50%	1,100
95%	110
96%	88
97%	66
98%	44
99%	22

\*Number of *staphylococcus aureus* used to challenge  
the barrier fabric tested in ASTM F2101

- Is there a meaningful difference between a mask that offers a 95% BFE versus 99.7% BFE?

95% BFE indicates 5% of the aerosolized bacteria used in testing **passed through** the mask material



99.7% BFE indicates only 0.3% of the aerosolized bacteria **passed through** the mask material

# Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

## Particle Filtration Efficiency (PFE) ASTM F2299/ ASTM F2299M - 03 (Reapproved 2010)

Sub-micron particulate filtration efficiency at 0.1 micron

Effectiveness of a material to filter aerosol particles (latex particles)



Results are expressed in percentage (%) that does NOT pass through the fabric at a given aerosol flow rate

## What is Flammability ... why is it important?

The rate at which the material burns determines the level of flammability



## 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles (Flame Spread)

A minimum of a 3.5 second burn rate is required to pass with a Class 1 rating



leatherusa.org Accessed 3.9.11 36

*As of April 2011,*  
**ASTM Standard F2100-11**



## ASTM Standard F2100-11

- Five required tests remain the same
- Change...
  - From: "Performance Class" (Low, Moderate and High)
  - To:     **"Performance Level"** (1,2 and 3)\*
- Graphic of performance level REQUIRED on the labeling of the primary packaging

# Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)



### ASTM Standard F2100-11

Medical Face Mask Material Requirements  
by Performance LEVEL

CHARACTERISTIC	TEST	LEVEL 1 Barrier	
Resistance to penetration by synthetic blood, <i>minimum pressure in mm Hg for pass result</i>	ASTM F1862	80	
Differential pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	4.4.1.2 of MIL-M-36954C	< 4.0	
Bacterial filtration efficiency	ASTM F2101	≥ 95%	
Sub-micron particulate filtration efficiency at 0.1 micron	ASTM F2299	≥ 95%	
Flame spread	16 CFR Part 1610	Class 1	



### ASTM Standard F2100-11

Medical Face Mask Material Requirements  
by Performance LEVEL

CHARACTERISTIC	TEST	LEVEL 1 Barrier	LEVEL 2 Barrier
Resistance to penetration by synthetic blood, <i>minimum pressure in mm Hg for pass result</i>	ASTM F1862	80	120
Differential pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	4.4.1.2 of MIL-M-36954C	< 4.0	< 5.0
Bacterial filtration efficiency	ASTM F2101	≥ 95%	≥ 98%
Sub-micron particulate filtration efficiency at 0.1 micron	ASTM F2299	≥ 95%	≥ 98%
Flame spread	16 CFR Part 1610	Class 1	Class 1



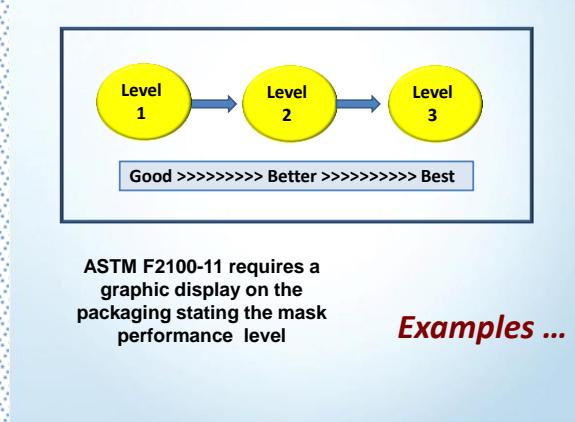
### ASTM Standard F2100-11

Medical Face Mask Material Requirements  
by Performance LEVEL

CHARACTERISTIC	TEST	LEVEL 1 Barrier	LEVEL 2 Barrier	LEVEL 3 Barrier
Resistance to penetration by synthetic blood, <i>minimum pressure in mm Hg for pass result</i>	ASTM F1862	80	120	160
Differential pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	4.4.1.2 of MIL-M-36954C	< 4.0	< 5.0	< 5.0
Bacterial filtration efficiency	ASTM F2101	≥ 95%	≥ 98%	≥ 98%
Sub-micron particulate filtration efficiency at 0.1 micron	ASTM F2299	≥ 95%	≥ 98%	≥ 98%
Flame spread	16 CFR Part 1610	Class 1	Class 1	Class 1

# Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)



ASTM Standard F2100-11

	Level 1	Level 2	Level 3
ASTM F1862 (Fluid Resistance)	80 mm Hg	120 mm Hg	160 mm Hg
MIL-M-36954 C: ΔP (Breathability)	< 4 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O
ASTM F2101: BFE (Filtration 3μm)	≥ 95%	≥ 98%	≥ 98%
ASTM F2299: PFE (Filtration 1μm)	≥ 95% @ 0.1 micron	≥ 98% @ 0.1 micron	≥ 98% @ 0.1 micron
16 CFR Part 1610: Flame Spread (Flammability)	Class 1	Class 1	Class 1

*Disclaimer:* This sample is for educational purposes only.

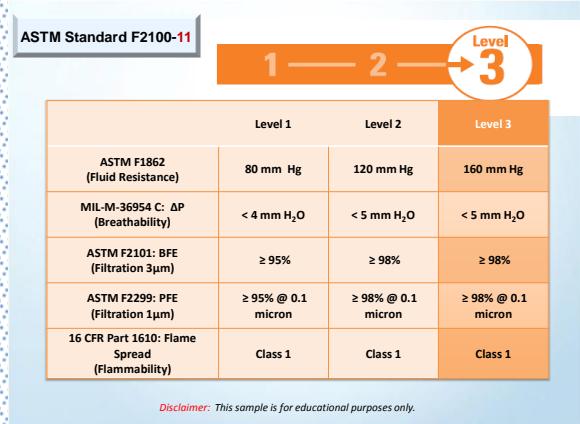
ASTM Standard F2100-11

	Level 1	Level 2	Level 3
ASTM F1862 (Fluid Resistance)	80 mm Hg	120 mm Hg	160 mm Hg
MIL-M-36954 C: ΔP (Breathability)	< 4 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O
ASTM F2101: BFE (Filtration 3μm)	≥ 95%	≥ 98%	≥ 98%
ASTM F2299: PFE (Filtration 1μm)	≥ 95% @ 0.1 micron	≥ 98% @ 0.1 micron	≥ 98% @ 0.1 micron
16 CFR Part 1610: Flame Spread (Flammability)	Class 1	Class 1	Class 1

*Disclaimer:* This sample is for educational purposes only.

# Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)



## What about masks already on the market?

Typically, the FDA does not apply standards retroactively.

If an FDA approved product is currently in the market with a specific performance class (*i.e., low barrier, moderate barrier, high barrier*) it will be allowed to stay.

## Which Mask Should You Choose?



# Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

## Considerations for Mask Selection



Follow appropriate precautions

(i.e. standard, contact, droplet, airborne)

## Considerations for Mask Selection

Precautions	Applies to	Mask selection
Standard	All Patients	Dependent upon: <ul style="list-style-type: none"><li>• HCW-patient interaction</li><li>• Anticipated blood/body fluid/pathogen exposure</li></ul>

CDC/HICPAC 2007 Guideline: Preventing Transmission of Infectious Agents in Health Care Settings.

## Considerations for Mask Selection

Precautions	Applies to	Mask selection
Standard	All patients	Dependent upon: <ul style="list-style-type: none"><li>• HCW-patient interaction</li><li>• Anticipated blood/body fluid/pathogen exposure</li></ul>
Contact	Patients with a disease/condition transmitted via contact (e.g., <i>Clostridium difficile</i> , head lice)	Dependent upon: <ul style="list-style-type: none"><li>• HCW-patient interaction</li><li>• Anticipated blood/body fluid/pathogen exposure</li><li>• Pathogen</li></ul>

CDC/HICPAC 2007 Guideline: Preventing Transmission of Infectious Agents in Health Care Settings.

Check the Label: Is the Mask a Level 1, 2, or 3?  
(... and What's the Difference?)

March 21, 2012 Webinar (Excellenia – ASC focus)

## Considerations for Mask Selection

Precautions	Applies to	Mask selection
Standard	All patients	Dependent upon: <ul style="list-style-type: none"><li>• HCW-patient interaction</li><li>• Anticipated blood/body fluid/pathogen exposure</li></ul>
Contact	Patients with a disease/condition transmitted via contact (e.g., <i>clostridium difficile</i> , head lice)	Dependent upon: <ul style="list-style-type: none"><li>• HCW-patient interaction</li><li>• Anticipated blood/body fluid/pathogen exposure</li><li>• Pathogen</li></ul>
Droplet (>5 microns)	Patients with a disease/condition transmitted via droplets (e.g., whooping cough, adenovirus, rhinovirus)	Wear a mask for close contact with infectious patient

CDC/HICRAC 2007 Guideline: Preventing Transmission of Infectious Agents in Health Care Settings

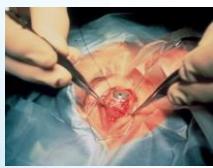
How do you know if your mask will protect you from infectious microorganisms?

Look at the package!



The new ASTM F2100-11 standard requires a graphic display on the packaging stating the mask performance level.

## Considerations for Mask Selection



Procedure: Anticipate **low amounts** of blood/fluid, spray and/or aerosol exposure

**Possible Procedures *include*\*:**

- simple excisional biopsies
- ophthalmological procedures
- simple ear, nose, and throat procedures

\* These examples are not intended to be all-inclusive or intended to be a substitute for professional judgment and experience.

Association for the Advancement of Medical Instrumentation (2005). Selection and use of protective apparel and surgical drapes in health care facilities. *AAMI TIR11:2005*.

# Check the Label: Is the Mask a Level 1, 2, or 3?

(... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

## Considerations for Mask Selection



Procedure: Anticipate **low** amounts of blood/fluid, spray and/or aerosol exposure

	Level 1	Level 2	Level 3
ASTM F1862 (Fluid Resistance)	80 mm Hg	120 mm Hg	160 mm Hg
MIL-M-36954 C: ΔP (Breathability)	< 4 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O
ASTM F2101: BFE (Filtration 3μm)	≥ 95%	≥ 98%	≥ 98%
ASTM F2299: PFE (Filtration 1μm)	≥ 95% @ 0.1 micron	≥ 98% @ 0.1 micron	≥ 98% @ 0.1 micron
16 CFR Part 1610: Flame Spread (Flammability)	Class 1	Class 1	Class 1

Level 1 mask as determined by ASTM F2100-11

## Considerations for Mask Selection



Procedure: Anticipate **moderate** amounts of blood/fluid, spray and/or aerosol exposure

Possible Procedures *include*\*:

- Arthroscopic orthopedic procedures
- Endoscopic urological procedures

\* These examples are not intended to be all-inclusive or intended to be a substitute for professional judgment and experience.

Association for the Advancement of Medical Instrumentation (2005). Selection and use of protective apparel and surgical drapes in health care facilities. AAMI TIR11:2005.

## Considerations for Mask Selection



Procedure: Anticipate **moderate** amounts of blood/fluid, spray and/or aerosol exposure

	Level 1	Level 2	Level 3
ASTM F1862 (Fluid Resistance)	80 mm Hg	120 mm Hg	160 mm Hg
MIL-M-36954 C: ΔP (Breathability)	< 4 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O
ASTM F2101: BFE (Filtration 3μm)	≥ 95%	≥ 98%	≥ 98%
ASTM F2299: PFE (Filtration 1μm)	≥ 95% @ 0.1 micron	≥ 98% @ 0.1 micron	≥ 98% @ 0.1 micron
16 CFR Part 1610: Flame Spread (Flammability)	Class 1	Class 1	Class 1

Level 2 mask as determined by ASTM F2100-11

# Check the Label: Is the Mask a Level 1, 2, or 3?

(... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

## Considerations for Mask Selection



Procedure: Anticipate **high amounts** of blood/fluid, spray and/or aerosol exposure

Possible Procedures *include*\*:

- Orthopedic procedures without a tourniquet
- Trauma procedures
- Caesarean sections

\* These examples are not intended to be all-inclusive or intended to be a substitute for professional judgment and experience.

Association for the Advancement of Medical Instrumentation (2005). Selection and use of protective apparel and surgical drapes in health care facilities. [AAMI TIR11:2005](#).

## Considerations for Mask Selection



Procedure: Anticipate **high amounts** of blood/fluid, spray and/or aerosol exposure

	Level 1	Level 2	Level 3
ASTM F1862 (Fluid Resistance)	80 mm Hg	120 mm Hg	160 mm Hg
MIL-M-36954C: ΔP (Breathability)	< 4 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O	< 5 mm H <sub>2</sub> O
ASTM F2101: BFE (Filtration 3μm)	≥ 95%	≥ 98%	≥ 98%
ASTM F2299: PFE (Filtration 1μm)	≥ 95% @ 0.1 micron	≥ 98% @ 0.1 micron	≥ 98% @ 0.1 micron
16 CFR Part 1610: Flame Spread (Flammability)	Class 1	Class 1	Class 1

Level 3 mask as determined by ASTM F2100-11

## Considerations for Mask Selection

Precautions	Applies to	Mask selection
Standard	All patients	Dependent upon: <ul style="list-style-type: none"><li>• HCW-patient interaction</li><li>• Anticipated blood/body fluid/pathogen exposure</li></ul>
Contact	Patients with a disease/condition transmitted via contact (e.g., <i>Clostridium difficile</i> , head lice)	Dependent upon: <ul style="list-style-type: none"><li>• HCW-patient interaction</li><li>• Anticipated blood/body fluid/pathogen exposure</li><li>• Pathogen</li></ul>
Droplet (>5 microns)	Patients with a disease/condition transmitted via droplets (e.g., whooping cough, adenovirus, rhinovirus)	Wear a mask for close contact with infectious patient
Airborne (droplet nuclei: ≤5 microns)	Patients with a disease/condition transmitted via droplet nuclei (e.g., chicken pox, M. tuberculosis)	Wear N95 or higher level respirator with infectious patient

CDC/HICPAC 2007 Guideline: Preventing Transmission of Infectious Agents in Health Care Settings.

Check the Label: Is the Mask a Level 1, 2, or 3?

(... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)



***Check the Label: Is the Mask a Level 1, 2, or 3?***

## POLL QUESTION

Before today, were you aware of ASTM F2100 and its role in identifying levels of barrier performance?

- Yes
- Not Sure
- No



**Check the Label: Is the Mask a Level 1, 2, or 3?**

## POLL QUESTION

Given the information just reviewed on performance barrier levels as defined by ASTM F2100-11, what mask would you choose to wear most frequently on a daily basis:

- Level 1
- Level 2
- Level 3
- Not Sure
- Need more information



**Check the Label:** Is the Mask a Level 1, 2, or 3?

## POLL QUESTION

In the future, you will look for the ASTM F2100 level of barrier performance on the mask packaging.

- Yes
- No
- Not Sure
- Need more information

# Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

**ASTM F2100:**  
Standard Specification for  
Performance of Materials Used in Medical Face Masks

***It is the responsibility of the user to establish appropriate safety and health practices***

ASTM F2100-11

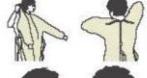
**Mask (donning).**

- Secure ties or elastic band at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin

**DONNING PPE**

**GOWN**

- Fully cover torso from neck to knee; arms to end of wrist, and wrap around the back.
- Fasten in back at neck and waist.



**MASK OR RESPIRATOR**

- Secure ties or elastic band at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator



**GOOGLES/FACE SHIELD**

- Put on face and adjust to fit



**GLOVES**

- Use non-sterile for isolation
- Select according to hand size
- Extend to cover wrist of isolation gown



**SAFE WORK PRACTICES**

- Keep hands away from face
- Wash hands before and after
- Limit surfaces touched
- Change when torn or heavily contaminated
- Perform hand hygiene

CDC/HICPAC 2007 Guideline - Preventing Transmission of Infectious Agents in Health Care Settings

**Check the Label: Is the Mask a Level 1, 2, or 3?**

**POLL QUESTION**

I always ensure that the mask I don fits correctly and completely covers my nose and mouth.

Strongly agree  
 Agree  
 Unsure  
 Disagree  
 Strongly disagree  
 Haven't thought about it

# Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

**Mask (donning)**

- Secure ties or elastic band at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin

**Safe Work Practices**

- Keep hands away from face
- Work from clean to dry
- Limit surfaces touched
- Change when torn or heavily contaminated
- Perform hand hygiene

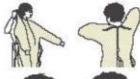
**CDC/HCPAC 2007 Guideline - Preventing Transmission of Infectious Agents in Health Care Settings**

**Figure. Example of Safe Donning and Removal of Personal Protective Equipment (PPE)**

**DONNING PPE**

**GOWN**

- Fully cover torso from neck to knees, arms to end of wrist, and wrap around the back
- Fasten in back at neck and waist



**MASK OR RESPIRATOR**

- Secure ties or elastic band of middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator



**GOGGLES/FACE SHIELD**

- Put on face and adjust to fit



**GLOVES**

- Use non-sterile for isolation
- Select according to hand size
- Extend to cover wrist of isolation gown



**SAFE WORK PRACTICES**

- Keep hands away from face
- Work from clean to dirty
- Limit surfaces touched
- Change when torn or heavily contaminated
- Perform hand hygiene

## Don't Defeat The Purpose Of Protection

The mask should:

- cover both the nose and the mouth



The mask should NOT be:

- worn under the chin or on top of the head
- worn as a necklace
- carried in your pocket for reuse



## How often should I change my mask?

The CDC recommends changing your mask:

- between patients
- during patient treatment if the mask becomes wet



Center for Disease Control. <http://www.cdc.gov/mmwr/preview/mmwrhtml/r5217a1.htm> Accessed 8.8.11

# Check the Label: Is the Mask a Level 1, 2, or 3?

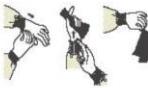
(... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

**REMOVING PPE**  
Remove PPE at doorway before leaving patient room or in anteroom

**GLOVES**

- Outside of gloves are contaminated
- Grasp outside of glove with opposite gloved hand; peer off
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist



**GOGGLES/FACE SHIELD**

- Outside of goggles or face shield are contaminated
- To remove, handle by "clean" head band or ear pieces
- Place in designated receptacle for reprocessing or in waste container



**GOWN**

- Gown front and sleeves are contaminated
- Unfasten neck, then waist ties
- Remove gown using a peeling motion, pull gown from each shoulder toward the same hand
- Gown will turn inside out
- Hold removed gown away from body, roll into a bundle and discard into waste or linen receptacle



**MASK OR RESPIRATOR**

- Front of mask/respirator is contaminated – DO NOT TOUCH!
- Grasp ONLY bottom then top ties/elastics and remove
- Discard in waste container



**HAND HYGIENE**

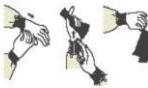
Perform hand hygiene immediately after removing all PPE!

CDC/HICPAC 2007 Guideline - Preventing Transmission of Infectious Agents in Health Care Settings

**REMOVING PPE**  
Remove PPE at doorway before leaving patient room or in anteroom

**GLOVES**

- Outside of gloves are contaminated
- Grasp outside of glove with opposite gloved hand; peer off
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist



**GOGGLES/FACE SHIELD**

- Outside of goggles or face shield are contaminated
- To remove, handle by "clean" head band or ear pieces
- Place in designated receptacle for reprocessing or in waste container



**GOWN**

- Gown front and sleeves are contaminated
- Unfasten neck, then waist ties
- Remove gown using a peeling motion, pull gown from each shoulder toward the same hand
- Gown will turn inside out
- Hold removed gown away from body, roll into a bundle and discard into waste or linen receptacle



**MASK OR RESPIRATOR**

- Front of mask/respirator is contaminated – DO NOT TOUCH!
- Grasp ONLY bottom then top ties/elastics and remove
- Discard in waste container



**HAND HYGIENE**

Perform hand hygiene immediately after removing all PPE!

CDC/HICPAC 2007 Guideline - Preventing Transmission of Infectious Agents in Health Care Settings

**Check the Label: Is the Mask a Level 1, 2, or 3?**

**Key Points**

 ASTM F2100 is the "Standard Specification for Performance of Materials Used in Medical Face Masks"

## Check the Label: Is the Mask a Level 1, 2, or 3? (... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)

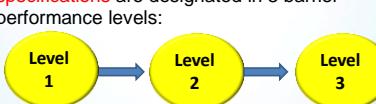
	<p><b>Check the Label: Is the Mask a Level 1, 2, or 3?</b></p> <h2>Key Points</h2> <ul style="list-style-type: none"><li>☞ ASTM F2100 is the "Standard Specification for Performance of Materials Used in Medical Face Masks"</li><li>☞ ASTM F2100 was updated in 2011 to communicate the expected barrier performance level</li></ul>



**Check the Label: Is the Mask a Level 1, 2, or 3?**

## Key Points

Medical face masks tested under **ASTM F2100-11 specifications** are designated in 3 barrier performance levels:



Good >>>>> Better >>>>> Best

**NOTE: 3 BARRIER LEVELS** recognized by this updated **ASTM Standard**

Check the Label: Is the Mask a Level 1, 2, or 3?  
(... and What's the Difference?)

March 21, 2012 Webinar (Excellentia – ASC focus)



**Check the Label: Is the Mask a Level 1, 2, or 3?**

## Key Points

	Look for the ASTM F2100-11 barrier level on the medical mask packaging
	Use this information to assist with appropriate mask selection

	<p><b>Check the Label: Is the Mask a Level 1, 2, or 3?</b></p> <h2>Key Points</h2> <table border="1"><tr><td></td><td>Look for the ASTM F2100-11 barrier level on the medical mask packaging</td></tr><tr><td></td><td>Use this information to assist with appropriate mask selection</td></tr><tr><td></td><td>Establish and perform appropriate safety and health practices</td></tr></table>		Look for the ASTM F2100-11 barrier level on the medical mask packaging		Use this information to assist with appropriate mask selection		Establish and perform appropriate safety and health practices
	Look for the ASTM F2100-11 barrier level on the medical mask packaging						
	Use this information to assist with appropriate mask selection						
	Establish and perform appropriate safety and health practices						



**CHECK THE LABEL:**

*Is the Mask a Level 1, 2, or 3  
and ... what's the difference?*

**Thank you!**