



# AssureMask® Balance™

Masques de procédure  
à boucles auriculaires

## CONÇU POUR LE SECTEUR MÉDICAL

### L'équilibre parfait entre le confort et la protection

Les masques à boucles auriculaires AssureMask Balance offrent aux professionnels de la santé et aux autres travailleurs de première ligne l'équilibre idéal entre la protection dont ils ont besoin et la respirabilité et le confort qu'ils désirent. Fabriqués à partir de matériaux de première qualité, ils protègent tout en évitant les ouvertures, l'inconfort ou l'irritation souvent causés par les masques fabriqués avec du matériel de moindre qualité.

Couleurs disponible: ● ● ● ●





# PROTECTION. CONFORT. RESPIRABILITÉ.



**Conception des plis de bardeaux** empêche l'accumulation de liquide et la contamination croisée



Fabriqué à partir de **matériaux de haute qualité** offrant une protection fiable sans compromettre la respirabilité



Disponible dans les **niveaux 1, 2 et 3 de l'ASTM**



**La barrette nasale réglable** assure un ajustement confortable et personnalisé



**Les boucles auriculaires scellées par ultrasons**, souples, extensibles et sans latex naturel évitent les tiraillements et les irritations

NIVEAU  
ASTM **1**

<b>205414</b> Blanc
<b>205415</b> Bleu
<b>205416</b> Rose
<b>205417</b> Jaune

50 masques/boîte  
10 boîtes/caisse

NIVEAU  
ASTM **2**

<b>205514</b> Blanc
<b>205515</b> Bleu
<b>205516</b> Rose
<b>205517</b> Jaune

50 masques/boîte  
10 boîtes/caisse

NIVEAU  
ASTM **3**

<b>205614</b> Blanc
<b>205615</b> Bleu
<b>205616</b> Rose
<b>205617</b> Jaune

50 masques/boîte  
10 boîtes/caisse

 **Medicom**® Fiers de protéger.

Comme vous, nous ne faisons jamais de compromis. Nous utilisons des matériaux soigneusement sélectionnés et concevons nos produits de manière à vous offrir une protection sur laquelle vous pouvez compter. Nous offrons la tranquillité d'esprit aux professionnels de la santé depuis plus de 30 ans. Nous sommes fiers de la protection que nous offrons, vous pouvez donc être fier de la vôtre.

Pour de plus amples renseignements, veuillez consulter [medicom.com](http://medicom.com) ou nous contacter à : [cservice@medicom.com](mailto:cservice@medicom.com) / 1-800-361-2862

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# AssureMask® Balance™

Procedure Earloop Face Masks

## MADE FOR MEDICAL

### The perfect balance between comfort and protection

AssureMask Balance earloop face masks provide healthcare professionals and other frontline workers with the ideal balance between the protection they need and the breathability and comfort they want. Made from high-quality materials, they protect without the gaping, discomfort or irritation often caused by masks made from lower-quality materials.

Available colours:    





# PROTECTION. COMFORT. BREATHABILITY.



**Shingle pleat design**  
prevents fluid pooling and  
cross-contamination



Made from **high-quality materials** that provide  
reliable protection without  
compromising breathability



Available in  
**ASTM levels 1, 2 and 3**



Adjustable nosepiece  
ensures a comfortable,  
**customized fit**



**Ultrasonically sealed,**  
**soft, stretchy, earloops**  
**free of natural rubber**  
**latex** prevent pulling and  
irritation

ASTM  
LEVEL **1**

**205414** White

**205415** Blue

**205416** Pink

**205417** Yellow

50 masks/box  
10 boxes/case

ASTM  
LEVEL **2**

**205514** White

**205515** Blue

**205516** Pink

**205517** Yellow

50 masks/box  
10 boxes/case

ASTM  
LEVEL **3**

**205614** White

**205615** Blue

**205616** Pink

**205617** Yellow

50 masks/box  
10 boxes/case

 **Medicom**® Pride in Protection.

Like you, we never compromise. We use carefully selected materials and engineer our products to offer protection you can count on. We have been providing peace of mind to healthcare professionals for over 30 years. We take pride in the protection we offer, so you can take pride in yours.

For more information, please visit [medicom.com](https://www.medicom.com) or contact us at:  
cservice@medicom.ca / 1-800-361-2862

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Quebec H9P 2Z2 Canada



# AssureMask® Balance™

ASTM  
LEVEL 3



## TECHNICAL DATA SHEET



### FEATURES & BENEFITS

- Non-woven spunbond outer layer provides maximum protection against fluid penetration.
- Soft, strong, ultrasonically sealed earloops attached to outside of mask prevent pulling and irritation and allow easy removal with less risk of self-contamination.
- Shingle pleat design prevents fluid pooling and cross-contamination.
- High-quality media ensures optimal filtration and breathability.
- Adjustable, enclosed nosepiece forms a strong seal to provide customized protection and comfort.

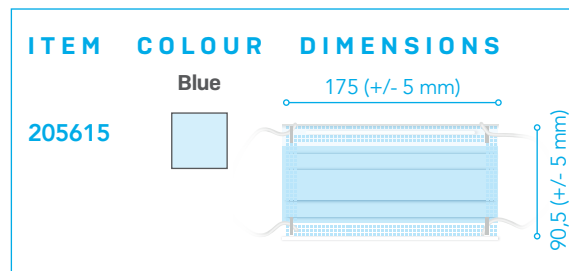
### RECOMMENDED USE

- Procedure masks are intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer. Latex free.

### PRODUCT DETAILS

Product Name:	<b>Medicom AssureMask® Balance™ Procedure Earloop Face Mask</b>
Product Type:	Single-use, non-sterile, three-layer construction
Earloop:	Polyester and spandex
Nosepiece:	Plastic-covered iron
Colour:	See Appendix 1
Quantity per Inner Carton:	50
Country of Origin:	China

DETAILED MASK DIMENSIONS	
Length of Earloop	165 mm
Pleat Depth	14 mm
Length of Nose-piece	105 mm



ASTM F2100 - LEVEL 3 BARRIER PROTECTION		
PERFORMANCE FACTORS	TEST METHODS	RESULT
Bacterial filtration efficiency (BFE)	ASTM F2101	≥ 98%
Sub-micron particulate efficiency at 0.1µm (PFE) /	ASTM F2299	≥ 98%
Resistant to penetration by synthetic blood	ASTM F1862	@ 160 mm Hg
Differential Pressure (ΔP)	EN 14683	< 6.0 mm H <sub>2</sub> O/cm <sup>2</sup>
Flame Spread	16 CF 1610	Class 1



### NON-WOVEN SPUNBOUND OUTER & INNER LAYER

Provides maximum protection against fluid penetration. Outer and inner layers made from spunbond polypropylene (SBPP).

### HIGH-QUALITY MEDIA

Ensures optimal filtration and breathability. Made from melt blown polypropylene (MBPP).

### SOFT, STRONG, ULTRASONICALLY SEALED EARLOOPS

Are attached to the outside of the mask to prevent pulling and irritation and allow easy removal with less risk of self-contamination.

### SOFT-BOND ULTRASONICS

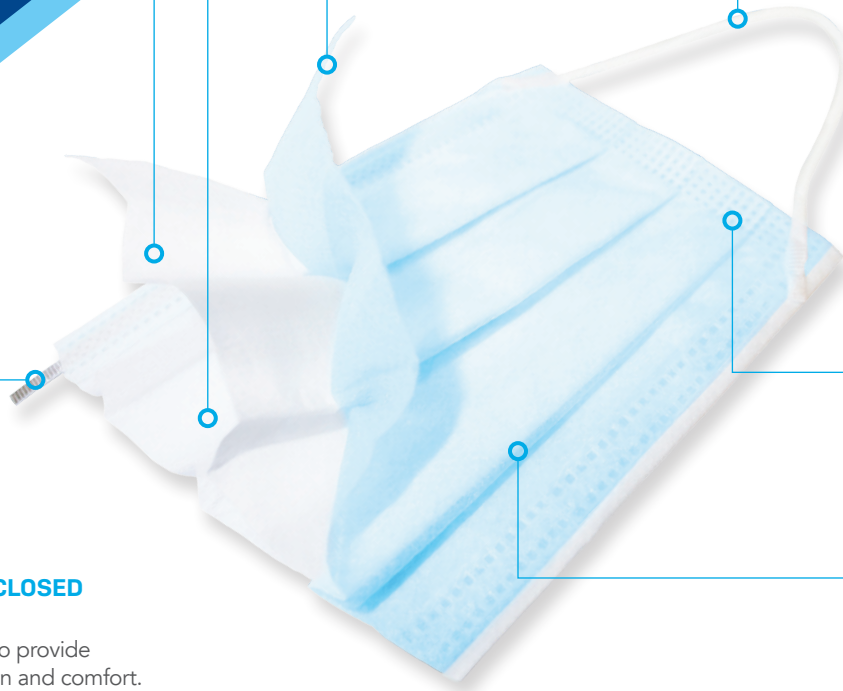
Ensure solid construction and eliminate holes and defects.

### SHINGLE PLEAT DESIGN

Prevents fluid pooling and cross-contamination. Mask must be worn with pleats facing down.

### ADJUSTABLE, ENCLOSED NOSEPIECE

Forms a strong seal to provide customized protection and comfort.



### AVAILABLE COLOURS

Blue



Pink



White



Yellow



## CERTIFICATION & STANDARDS

ISO 13485 certified manufacturer.  
Class 1 Medical Device.  
Health Canada registered medical device manufacturer.

## STORAGE CONDITIONS

These masks should be disposed of after each use.  
Store in a cool, dry place.  
Avoid excessive heat (40 °C or 104 °F).



## DONNING INSTRUCTIONS

- Fan to open pleats.
- Shape before applying to ensure a better fit.
- Pull earloops over each ear.
- With two fingers on either side of your nose, firmly shape around your nose and across your cheeks, concentrating on the bridge of your nose, to secure the seal.
- Pinch the nosepiece and make sure the base of the mask sits comfortably below your chin.

## DOFFING INSTRUCTIONS

- Pull the earloops off your ears.
- Pull the mask away from your face, taking care not to touch its outer surface.
- Still holding only the earloops and taking care not to touch outer surface, dispose of mask in a clinical waste bin.
- Always wash your hands thoroughly after removing a mask.



**Appendix 1 (List of items)**

<b>Item Code</b>	<b>Description</b>	<b>Packaging Information</b>	<b>Color</b>	<b>Specific Attribute</b>	<b>Treatment</b>	<b>Marketed in USA as</b>	<b>Marketed in Canada as</b>
205614	Medicom AssureMask Balance Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	White	Plastic Covered Iron Nose-piece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205615	Medicom AssureMask Balance Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Plastic Covered Iron Nose-piece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205616	Medicom AssureMask Balance Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Pink	Plastic Covered Iron Nose-piece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205617	Medicom AssureMask Balance Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Yellow	Plastic Covered Iron Nose-piece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1

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**FICHE TECHNIQUE**
**Masques de procédure avec boucles auriculaires : ASTM F2100 Niveau 3**
**Usage prévu**

Les masques de procédure sont destinés à être portés par le personnel pendant les procédures médicales afin de protéger à la fois le patient et le personnel opérant contre le transfert de micro-organismes, de fluides corporels et de particules. Sans latex.

ASTM F2100 – Protection barrière de niveau 3		
Caractéristique	Méthodologie	Limites acceptables
Efficacité de filtration bactérienne (BFE)	ASTM F2101	BFE @ 3.0 µm large Bacteria ≥ 95%
Pression différentielle (ΔP)	EN 14683	ΔP < 6.0 mm of H <sub>2</sub> O/cm <sup>2</sup>
Efficacité de filtration des particules (PFE)	ASTM F2299	PFE @ 0.1 µm large Latex particules ≥ 98%
Résistance aux fluides	ASTM F1862	Résistance @ 160mmHg
Inflammabilité du textile	16 CFR 1610	Class I flame spread

Caractéristique	Spécification		
Composition du matériau	Masque	Matériau extérieur	Spunbond Polypropylène (SBPP)
		Couche filtrante	Meltblown Polypropylène (MBPP)
		Matériau intérieur	Spunbond Polypropylène (SBPP)
	Barrette nasale	Bande de fer recouverte de plastique	
	Boucles auriculaires	Polyester et Spandex	
Description	Masques faciaux rectangulaires à plis de bardeaux avec une barrette nasale modulable et deux boucles auriculaires, une de chaque côté, afin de maintenir le masque en place.		
Couleur	Référer à l'annexe 1.		
Style de contour d'oreille	Tricot plat		
Attributs	Taille du corps	Longueur	175 mm (6 7/8")
		Largeur	90,5 mm (3 1/2")
	Longueur des boucles	165 mm (6 1/2")	
	Profondeur de pli	14 mm (5/8")	
	Longueur de la barrette nasale	105 mm (4 1/8")	

## Image du produit



## Information additionnelle

Condition de stockage	Pays d'origine
Conserver dans des conditions fraîches, propres et sèches. Évitez la chaleur excessive (supérieure à 40 ° C ou 104 ° F).	Chine



## Annexe 1 (Liste des codes d'items)

*AMD Medicom Inc.*

Code d'item	Description	Information d'emballage	Couleur	Attribut spécifique	Traitement	Marché États-Unis	Marché Canada
205614	Medicom AssureMask Balance Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	White	Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205615	Medicom AssureMask Balance Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205616	Medicom AssureMask Balance Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Pink	Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205617	Medicom AssureMask Balance Procedure Earloop Face Masks, L3	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Yellow	Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1