



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**

205414 Blanc
205415 Bleu
205416 Rose
205417 Jaune

50 masques/boîte
10 boîtes/caisse

NIVEAU
ASTM **2**

205514 Blanc
205515 Bleu
205516 Rose
205517 Jaune

50 masques/boîte
10 boîtes/caisse

NIVEAU
ASTM **3**

205614 Blanc
205615 Bleu
205616 Rose
205617 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 ou nous contacter à : cservice@medicom.com / 1-800-361-2862

AMD Medicom Inc. 2555, Chemin de l'Aviation, Pointe-Claire, Montréal, Québec H9P 2Z2 Canada



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 or contact us at:
cservice@medicom.ca / 1-800-361-2862

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Quebec H9P 2Z2 Canada

AssureMask® Balance™

ASTM
LEVEL 2



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.

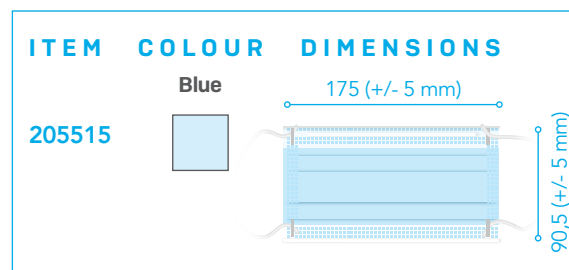
RECOMMENDED USE

- 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:	Medicom AssureMask® Balance™ Procedure Earloop Face Mask
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 2 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	@ 120 mm Hg
Differential Pressure (ΔP)	EN 14683	< 6.0 mm H ₂ O/cm ²
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

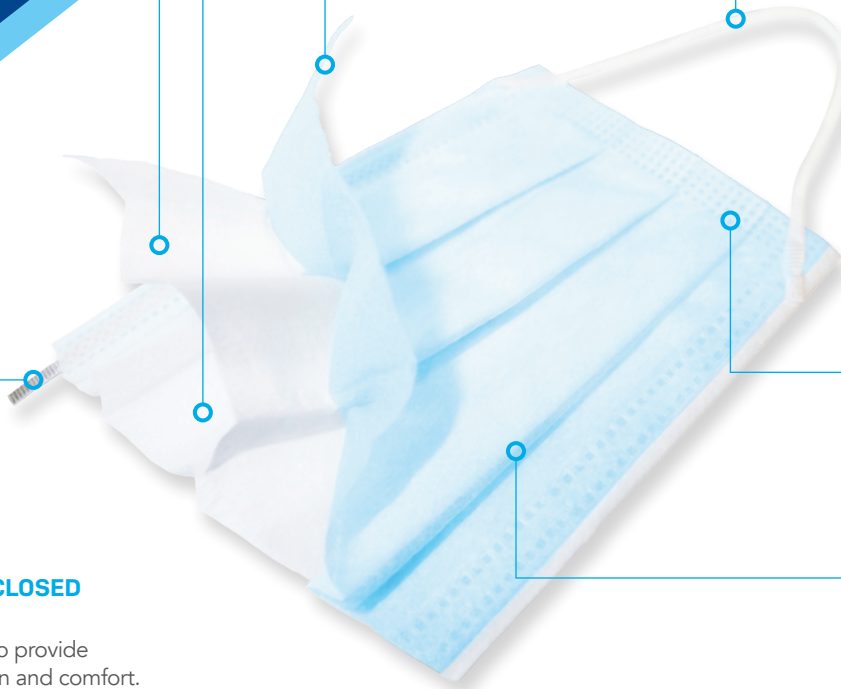
Ensure solid construction and eliminate holes and defects.

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)

Item Code	Description	Packaging Information	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
205514	Medicom AssureMask Balance Procedure Earloop Face Masks, L2	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	White	Plastic Covered Iron Nosepiece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205515	Medicom AssureMask Balance Procedure Earloop Face Masks, L2	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Plastic Covered Iron Nosepiece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205516	Medicom AssureMask Balance Procedure Earloop Face Masks, L2	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Pink	Plastic Covered Iron Nosepiece, Flat Knitted Earloop, Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205517	Medicom AssureMask Balance Procedure Earloop Face Masks, L2	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Yellow	Plastic Covered Iron Nosepiece, 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 2
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 2		
Caractéristique	Méthodologie	Limites acceptables
Efficacité de filtration bactérienne (BFE)	ASTM F2101	BFE @ 3.0 µm large Bacteria ≥ 98%
Pression différentielle (ΔP)	EN 14683	ΔP < 6.0 mm of H ₂ O/cm ²
Efficacité de filtration des particules (PFE)	ASTM F2299	PFE @ 0.1 µm large Latex particules ≥ 98%
Résistance aux fluides	ASTM F1862	Résistant @ 120mmHg
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 polypropylène (plastique)	
	Boucles auriculaires	Polyester et Spandex	
Description	Masques faciaux rectangulaires à plis de bardeaux avec une barrette nasale modulable et deux boucles auriculaires, un de chaque côté, afin de maintenir le masque en place.		
Couleur	Référer à l'annexe 1		
Boucles auriculaires	Tricoté plat		
Dimensions	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 de codes d'items et attributs

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
205514	Medicom AssureMask Balance Procedure Earloop Face Masks, L2	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	White	Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205515	Medicom AssureMask Balance Procedure Earloop Face Masks, L2	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Blue	Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205516	Medicom AssureMask Balance Procedure Earloop Face Masks, L2	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Pink	Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1
205517	Medicom AssureMask Balance Procedure Earloop Face Masks, L2	50 Masks/Box, 10 Boxes/Case, 500 Masks/Case	Yellow	Regular Earloop Length	Non-Sterile	Medical Device Class 2	Medical Device Class 1