

ResMed Mask Materials December 2010-12-16

PRODUCT BULLETIN

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Replaces Product Bulletin #605

Following are details of the materials contained in ResMed Full Face Mask, Nasal Mask and Nasal Pillows systems. Please note some products may not be available in all regions.

As a manufacturer of medical devices, ResMed's products are subject to strict regulation. One of the requirements in this regard is to demonstrate an appropriate level of biocompatibility for every material to which a patient is exposed. To this end, the biocompatibility of each of the materials listed below has been confirmed by ResMed.

ResMed mask cushions are made from silicone which is a hypoallergenic material used in medical appliances and devices. True allergic reactions to silicone are extremely rare. In fact, skin irritation, sores (pressure sores) and blisters are more commonly caused by other associated factors rather than the silicone material itself.

Further information and advice regarding skin irritation resulting from the use of CPAP masks can be found at the following website www.resmed.com, enter 'skin irritation' in the search field to find the latest information.

Quattro™ FX Full Face Mask / Quattro™ FX Non-Vented Full Face Mask

Component	Material
Frame	Polycarbonate
Swivel	15% PTFE in Polycarbonate
Elbow	Polycarbonate (NV has blue tint)
Headgear Clip	Polyester (PBT)
Ports Cap	Silicone Elastomer
Mask Cushion	Silicone Elastomer
Valve	Silicone Elastomer
Valve Clip	Polycarbonate
Headgear	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>Cloth Label:</i> Rayon acetate satin
Soft Sleeves	88% Nylon / 12% Spandex

Mirage™ FX Nasal Mask

Component	Material
Cushion	Hard: Nylon Soft: Silicone
Frame	Hard: Nylon Soft: Silicone
Elbow	Hard: Nylon Hard: Polypropylene Soft: Thermoplastic Elastomer
Headgear	Fabric: Nylon/Lycra Foam: Polyurethane Foam

Swift™ FX Nasal Pillows System

Component	Material
Pillows	Silicone Elastomer
Headgear Assembly	<i>Headgear:</i> Silicone Elastomer <i>Backstrap:</i> Foam Layer: Open cell Polyurethane Fabric: Nylon/Spandex
Short Tube Assembly	<i>Elbow Swivel:</i> Polycarbonate <i>Elbow:</i> Polypropylene <i>Short-tube:</i> Thermoplastic Polyester Elastomer (TPE) <i>Swivel Assembly:</i> Polycarbonate/Polypropylene
Soft Wraps	Polyester

Mirage™ SoftGel Nasal Mask

Component	Material
Frame	Polycarbonate
Clear Dial	Polycarbonate
Dial - Sleep Lab Kit	15% PTFE in Polycarbonate
Elbow	Polycarbonate
Headgear Clip	Polycarbonate
Forehead Support	Polycarbonate
Swivel	15% PTFE in Polycarbonate
Ports Cap	Silicone Elastomer
Cushion	Bladder: Silicone Elastomer Gel (both layers): Silicone Gel Sealing bead: Silicone Elastomer
Cushion Clip	Polyester
Forehead Pad	Silicone Elastomer
Headgear Assembly	<i>Elastomer Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>Cloth Label:</i> Rayon acetate satin



Mirage Activa™ LT Nasal Mask

Component	Material
Frame	Polycarbonate
Clear Dial	Polycarbonate
Dial - Sleep Lab Kit	15% PTFE in Polycarbonate
Elbow	Polycarbonate
Headgear Clip	Polycarbonate
Forehead Support	Polycarbonate
Swivel	15% PTFE in Polycarbonate
Ports Cap	Silicone Elastomer
Cushion	Silicone Elastomer
Cushion Clip	Polyester
Forehead Pad	Silicone Elastomer
Headgear Assembly	<i>Elastomer Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>Cloth Label:</i> Rayon acetate satin

Swift™ LT for Her Nasal Pillows System

Component	Material
Frame	Silicone Elastomer
Cushion (Pillows)	Silicone Elastomer
Headgear Assembly	<i>Headgear Straps:</i> Foam Layer: Open cell Polyurethane Fabric: Nylon/Spandex <i>Buckles:</i> Thermoplastic Polyester Elastomer (TPE) <i>Yokes:</i> Nylon
Elbow	Polypropylene
Inlet Tube	Thermoplastic Polyester Elastomer (TPE)
Swivel Assembly	Polycarbonate/Polypropylene
Plastic Tube Retainer	Thermoplastic Polyester Elastomer (TPE)
Soft Wraps	Polyester

Swift™ LT Nasal Pillows System

Component	Material
Frame	Silicone Elastomer
Cushion (Pillows)	Silicone Elastomer
Headgear Assembly	<i>Headgear Straps:</i> Foam Layer: Open cell Polyurethane Fabric: Nylon/Spandex <i>Buckles:</i> Thermoplastic Polyester Elastomer (TPE) <i>Yokes:</i> Nylon
Elbow	Polypropylene
Inlet Tube	Thermoplastic Polyester Elastomer (TPE)
Swivel Assembly	Polycarbonate/Polypropylene
Plastic Tube Retainer	Thermoplastic Polyester Elastomer (TPE)

Mirage Micro™ Nasal Mask

Component	Material
Frame	Polycarbonate
Clear Dial	Polycarbonate
Dial - Sleep Lab Kit	15% PTFE in Polycarbonate
Elbow	Polycarbonate
Headgear Clip	Polycarbonate
Forehead Support	Polycarbonate
Swivel	15% PTFE in Polycarbonate
Ports Cap	Silicone Elastomer
Cushion	Silicone Elastomer
Forehead Pad	Silicone Elastomer
Headgear Assembly	Elastomer Layer: Open cell Polyurethane Loop Material: Nylon/Spandex Underside Fabric: Nylon/Spandex Fastener Tabs: Polycaprolactam (Polyamide Family) Cloth Label: Rayon acetate satin

Mirage Liberty™ Full Face Mask

Component	Material
Frame	Polycarbonate
Elbow	Polycarbonate
Ports Cap	Silicone Elastomer
Cushion	Silicone Elastomer
Pillows	Silicone Elastomer
Valve	Silicone Elastomer
Valve Clip	Polycarbonate
Short Tube	<i>Material Tube:</i> Polyolefin Plastomer (POP) <i>Material Cuff:</i> SEBS Based Thermoplastic Elastomer – Light Grey
Swivel Assembly	Polycarbonate/Polypropylene
Headgear	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam <i>Cloth Label:</i> Rayon acetate satin
Upper Headgear Clip Assembly	<i>Upper Clips:</i> Nylon <i>Foam Layer:</i> Open cell Polyurethane <i>Underside Fabric:</i> Nylon/Spandex <i>Stitching:</i> Nylon Anafil
Lower Headgear Clip	Polyester (PBT)

Mirage Quattro™ Full Face Mask

Component	Material
Frame	Polycarbonate
Cushion Clip	Polyester (PBT)
Swivel	15% PTFE in Polycarbonate
Elbow	Polycarbonate
Forehead Support	Polycarbonate
Headgear Clip	Polyester (PBT)
Ports Cap	Silicone Elastomer
Forehead Support Pad	Silicone Elastomer
Dial	Polycarbonate
Dial - Sleep Lab Kit	15% PTFE in Polycarbonate
Mask Cushion	Silicone Elastomer
Valve	Silicone Elastomer
Valve Clip	Polycarbonate
Headgear	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>Cloth Label:</i> Rayon acetate satin

Mirage Swift™ and Mirage Swift™ II Nasal Pillows System

Component	Material
Frame	Polypropylene
Cushion Clip	Polypropylene
Seal Ring	Silicone Elastomer
Elbow	Polypropylene
Inlet Tube	Polyolefin Plastomer (POP)
Tube Retainer	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam
Swivel Assembly	Polycarbonate/Polypropylene
Snap Plug	Polypropylene
Cushion	Silicone Elastomer
Headgear Assembly	<i>Headgear Straps:</i> Foam Layer: Open cell Polyurethane Fabric: Nylon/Spandex <i>Headgear Buckle:</i> Nylon <i>Yokes:</i> Nylon



Mirage Kidsta™ Nasal Mask

Component	Material
Elbow	Polycarbonate
Frame	Polycarbonate
Short Tube	<i>Material Tube:</i> Polyolefin plastomer (POP) <i>Material Cuff:</i> SEBS Based Thermoplastic Elastomer – Light Grey
Swivel Assembly	Polycarbonate/Polypropylene
Exhaust Vent	Silicone Elastomer
Cushion	Silicone Elastomer
Ports Cap	Silicone Elastomer
Headgear Assembly	<i>Headgear Straps:</i> Foam Layer: Open cell Polyurethane Fabric: Nylon/Spandex <i>Headgear Clip:</i> Polypropylene <i>Yokes:</i> Nylon <i>Ladder Lock:</i> Nylon <i>Crossover:</i> Nylon <i>Strap Loop:</i> Silicone Elastomer <i>Headgear Label:</i> Rayon acetate satin

Mirage Activa™ Nasal Mask

Component	Material
Frame	Polycarbonate
Elbow	Polycarbonate
Vent	Silicone Elastomer
Cushion Clip	Polyester
Headgear Clip	Polyester
Forehead T-Bar	Polycarbonate
Short Tube	<i>Material Tube:</i> Polyolefin Plastomer (POP) <i>Material Cuff:</i> SEBS Based Thermoplastic Elastomer – Light Grey
Swivel Assembly	Polycarbonate/Polypropylene
Ports Cap	Silicone Elastomer
Cushion	Silicone Elastomer
Forehead Pads	Silicone Elastomer
Cloth Label	Rayon acetate satin
Headgear Assembly	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>Cloth Label:</i> Rayon acetate satin

Ultra Mirage™ Full Face Mask

Component	Material
Frame	Polycarbonate
Cushion Clip	Polycarbonate
Swivel	Polycarbonate
Elbow	Polycarbonate
Lower Housing	Polycarbonate
Swivel Clip	Polycarbonate
Elbow Retainer	Polycarbonate
Forehead Support	Polycarbonate
Headgear Clip	Polyester (PBT)
Ports Cap	Polycarbonate
Forehead Pads	Silicone Elastomer
Cushion	Silicone Elastomer
Grommet	Silicone Elastomer
Valve Membrane	Silicone Elastomer
Headgear Assembly	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>Cloth Label:</i> Rayon acetate satin

Non-Vented Ultra Mirage™ Full Face Mask

Component	Material
Frame	Polycarbonate
Cushion Clip	Polycarbonate
Elbow	Polycarbonate
Elbow Retainer	Polycarbonate
Forehead Support	Polycarbonate
Headgear Clip	Polyester (PBT)
Ports Cap	Polycarbonate
Forehead Pads	Silicone Elastomer
Cushion	Silicone Elastomer
Headgear Assembly	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>Stiffening ribbon:</i> Satin polyester ribbon sewn inside <i>Cloth Label:</i> Rayon acetate satin



Mirage Vista™ Nasal Mask

Component	Material
Elbow	Polycarbonate
Frame	Polycarbonate
Short Tube	<i>Material Tube:</i> Polyolefin plastomer (POP) <i>Material Cuff:</i> SEBS Based Thermoplastic Elastomer – Light Grey
Swivel Assembly	Polycarbonate/Polypropylene
Exhaust Vent	Silicone Elastomer
Cushion	Silicone Elastomer
Ports Cap	Silicone Elastomer
Headgear Assembly	<i>Headgear Straps:</i> Foam Layer: Open cell Polyurethane Fabric: Nylon/Spandex <i>Headgear Clip:</i> Polypropylene <i>Yokes:</i> Nylon <i>Ladder Lock:</i> Nylon <i>Crossover:</i> Nylon <i>Strap Loop:</i> Silicone Elastomer <i>Headgear Label:</i> Rayon acetate satin

Mirage™ Full Face Mask Series 2 (Vented and Non-Vented)

Component	Material
Frame	Polycarbonate
Grommet	Silicone Elastomer
Cushion Clip	Polycarbonate
Elbow	Polycarbonate
Lower Housing	Polycarbonate
Swivel	Polycarbonate
Swivel Clip	Polycarbonate
Elbow Retainer	Polycarbonate
Forehead Pad Clip	Polycarbonate
Luer Lock Ports Cap	Polycarbonate
NV components	Polycarbonate
Valve Membrane	Silicone Elastomer
Cushion	Silicone Elastomer
Forehead Pad Shallow	Silicone Elastomer
Forehead Pad Deep	Silicone Elastomer
Cloth Label	Rayon acetate satin
NV Cloth Label	
Headgear Assembly NV Headgear Assembly	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>NV Assembly:</i> Satin tape sewn inside <i>Cloth Label:</i> Rayon acetate satin



Ultra Mirage™/Ultra Mirage™ II Nasal Mask (Vented and Non-Vented)

Component	Material
Frame	Polycarbonate
Elbow	Polycarbonate
Vent Cover	Polycarbonate
Cushion Clip	Polycarbonate
Headgear Clip	Polycarbonate
Elbow Clip	Polycarbonate
Forehead Support	Polycarbonate
NV components	Polycarbonate
Swivel	15% PTFE in Polycarbonate
Ports Cap	Silicone Elastomer
Cushion Standard	Silicone Elastomer
Forehead Pad	Silicone Elastomer
Cloth Label NV Cloth Label	Rayon acetate satin
Headgear Assembly NV Headgear Assembly	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>NV Assembly:</i> Satin polyester ribbon sewn inside <i>Cloth Label:</i> Rayon acetate satin

Mirage™ Nasal Mask (Vented and Non-Vented)

Component	Material
Frame	Polycarbonate
Connector Pipe	Polycarbonate
Swivel	Polycarbonate
T-bar	Polycarbonate
Actuator Arm	Polycarbonate
Small-Bore Tubing	Polyolefin
Small Bore Swivel Adapter	Polypropylene
NV Components	Polycarbonate
Ports Cap	Silicone Elastomer
Grommet	Silicone Elastomer
Cushion Standard	Silicone Elastomer
Forehead Pads	Silicone Elastomer
Cloth Label NV Cloth Label	Rayon acetate satin
Headgear Assembly NV Headgear Assembly	<i>Foam Layer:</i> Open cell Polyurethane <i>Loop Material:</i> Nylon/Spandex <i>Underside Fabric:</i> Nylon/Spandex <i>Fastener Tabs:</i> Polycaprolactam (Polyamide Family) <i>NV Assembly:</i> Satin tape sewn inside



Disposable Mask Systems

ResMed Hospital Disposable Non-Vented Full Face Mask

Component	Material
Cushion	Silicone Elastomer
Frame	Polypropylene
Cushion Clip	Polycarbonate
Elbow	Polycarbonate
Port Cap	Silicone Elastomer
Headgear Clip	Polyester (PBT)
Headgear	<i>Top Layer:</i> Polyester <i>Underside:</i> Polyester <i>Foam Layer:</i> Open cell Polyurethane <i>Finished Fabric:</i> Pressure lamination of the three layers of material using an acrylic adhesive

ResMed Hospital Non-Vented Full Face Mask

Component	Material
Frame	Polypropylene
Elbow	Polycarbonate
Cushion	Silicone Elastomer
Cushion Clip	Polycarbonate
Headgear Clip	Polyester (PBT)
Ports Cap	Silicone Elastomer
Headgear	<i>Top Layer:</i> Nylon <i>Underside:</i> Nylon <i>Foam Layer:</i> Open cell Polyurethane <i>Finished Fabric:</i> Pressure lamination of the three layers of material using an acrylic adhesive

ResMed Hospital Disposable Full Face Mask

Component	Material
Swivel	Polycarbonate
Distal Pressure Port	Polycarbonate
Cushion	Silicone Elastomer
Frame	Polypropylene
Elbow	Polyester (PBT)
Anti-asphyxia Valve	Silicone Elastomer
Cushion Clip	Polycarbonate
Headgear Clip	Polyester (PBT)
Headgear	<i>Top Layer:</i> Polyester <i>Underside:</i> Polyester <i>Foam Layer:</i> Open cell Polyurethane <i>Finished Fabric:</i> Pressure lamination of the three layers of material using an acrylic adhesive



ResMed Hospital Nasal Mask

Component	Material
Cushion	Silicone Elastomer
Frame	Polycarbonate
Cushion Clip	Polycarbonate
Elbow Assembly	<i>Lower Swivel:</i> Polypropylene <i>Elbow:</i> Polycarbonate
Headgear	White Elastic Button Hole Tape 70% Polyester 30% non Latex elastomer

For further information, please contact your nearest ResMed office. See www.resmed.com for details.

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PRODUCT BULLETIN SPECIFICATION

Rev	Change Note	Date Document Drafted	Document Prepared by (Name)	Document Checked by (Name)
1	C27542	Jan 10 2011	Mina Kirolos	Rosella Cherett

PRODUCT BULLETIN #679

ResMed Mask Materials December 2010-12-16

1. DETAILS

Brief Details:	Product Bulletin details materials contained in ResMed masks
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2. DISTRIBUTION

By Marketing Department to:	(i) Regional - Product Managers
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