



ResMed

AirFit™ F20

AirTouch™ F20

Full face mask



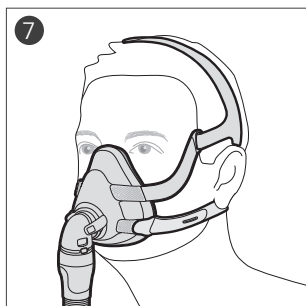
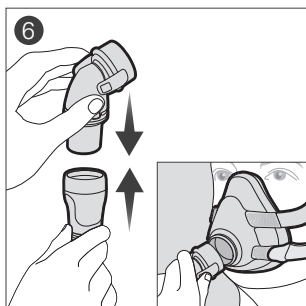
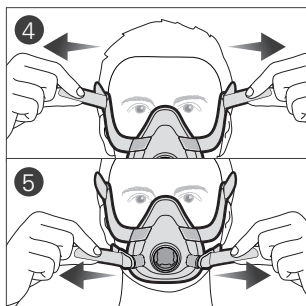
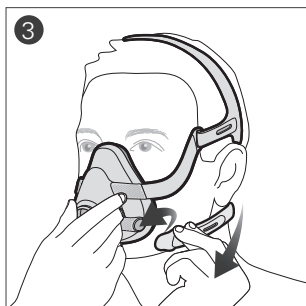
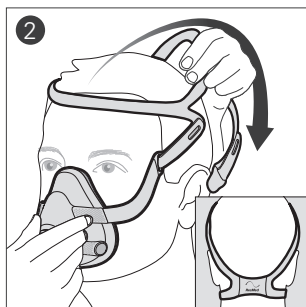
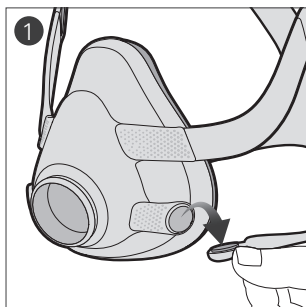
CPAPXCHANGE

SLEEP WELL TONIGHT

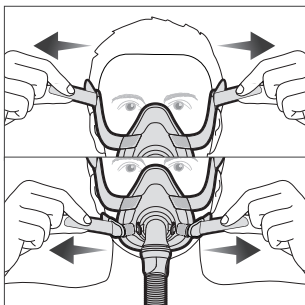
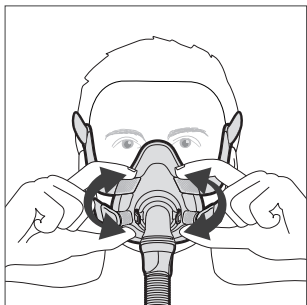
User guide

English

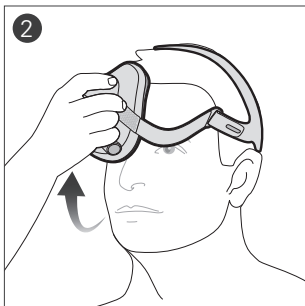
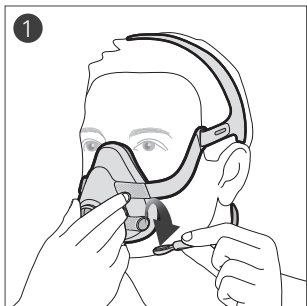
Fitting / Mise en place / Colocación / Colocação **R_x** Only



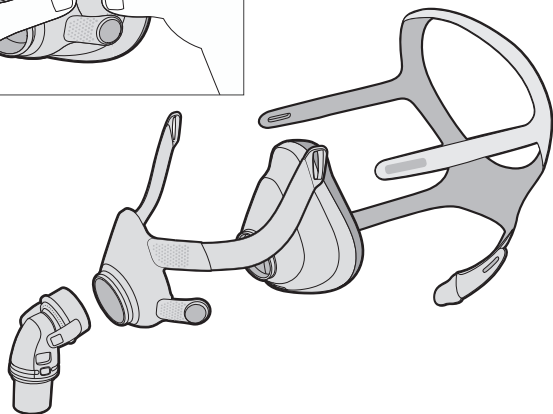
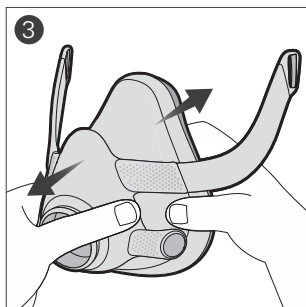
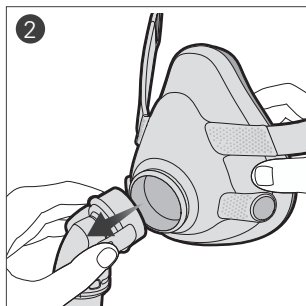
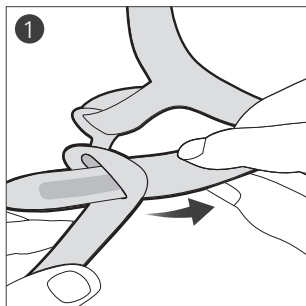
Adjustment / Ajustement / Ajuste / Ajuste



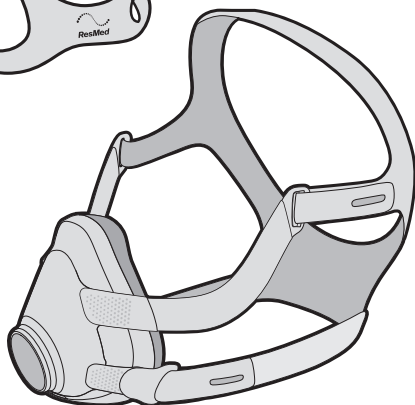
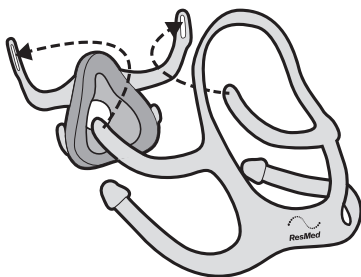
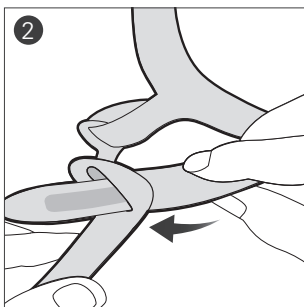
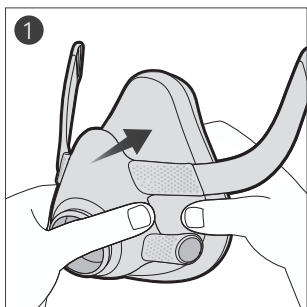
Removal / Retrait / Remoción / Remoção



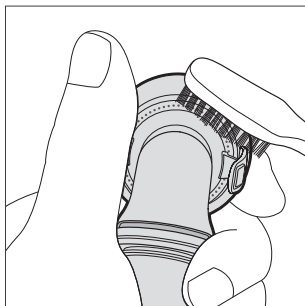
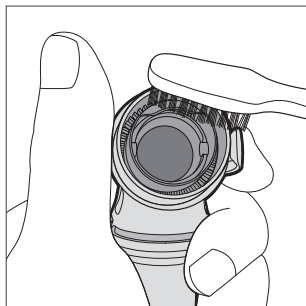
Disassembly / Démontage / Desensamblado /
Desmontagem



Reassembly / Remontage / Reensamblado / Remontagem



Cleaning the vent / Nettoyage de l'orifice de ventilation
/ Limpieza del orificio de ventilación / Limpeza do
respiradouro



AirFit™ F20

AirTouch™ F20

Full face mask

Thank you for choosing the AirFit™ F20/AirTouch™ F20. These masks are identical—except for the interchangeable AirFit F20 silicone cushion and AirTouch F20 foam cushion. This offers two choices for your mask, depending on your preferred comfort, stability and seal.

This document provides the user instructions for:

- AirFit™ F20/AirFit™ F20 for Her
- AirTouch™ F20/AirTouch™ F20 for Her

These masks are referred to collectively as F20 throughout this manual. These masks may not be available in all countries.

Using this guide

Please read the entire guide before use. When following instructions, refer to the images at the front of the guide.

Intended use

The F20 is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system.

The F20 is:

- to be used by patients weighing more than 66 lb (30 kg) for whom positive airway pressure therapy has been prescribed
- intended for single-patient reuse in the home environment and multi-patient reuse in the hospital/institutional environment.

AirTouch F20 cushion

The cushion is intended for single-patient reuse in both home and hospital/institutional environments and recommended to be replaced monthly.

WARNING

Magnets are used in the lower headgear straps and the frame of the F20. Ensure the headgear and frame is kept at least 2" (50 mm) away from any active medical implant (eg, pacemaker or defibrillator) to avoid possible effects from localized magnetic fields. The magnetic field strength is less than 400 mT.

Contraindications

Use of masks with magnetic components is contraindicated in patients with the following pre-existing conditions:

- a metallic hemostatic clip implanted in your head to repair an aneurysm
- metallic splinters in one or both eyes following a penetrating eye injury.

GENERAL WARNINGS

- The mask must be used under qualified supervision for users who are unable to remove the mask by themselves. The mask may not be suitable for those predisposed to aspiration.
- The mask must be fitted with the supplied elbow (containing the valve and vent assembly) to ensure safe and functional usage unless otherwise specified. Do not use the mask if the valve or vent assembly is damaged or missing.
- The elbow, valve and vent assembly have specific safety functions. The mask should not be worn if the valve is damaged as it will not be able to perform its safety function. The elbow should be replaced if the valve is damaged, distorted or torn. The vent holes and valve should be kept clear.
- The mask should only be used with CPAP or bilevel devices recommended by a physician or respiratory therapist.
- Avoid connecting flexible PVC products (eg, PVC tubing) directly to any part of the mask. Flexible PVC contains elements that can be damaging to the materials of the mask, and may cause the components to crack or break.
- The mask should not be used unless the device is turned on. Once the mask is fitted, ensure the device is blowing air.
Explanation: CPAP and bilevel devices are intended to be used with special masks (or connectors) which have venting to allow

continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask holes. When the device is turned off, the mask valve opens to atmosphere allowing fresh air to be breathed. However, a higher level of exhaled air may be rebreathed when the device is off. This applies to most full face masks for use with CPAP and bilevel devices.

- Follow all precautions when using supplemental oxygen.
- Oxygen flow must be turned off when the CPAP or bilevel device is not operating, so that unused oxygen does not accumulate within the device enclosure and create a risk of fire.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in well ventilated rooms.
- At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration varies, depending on the pressure settings, patient breathing pattern, mask, point of application and leak rate. This warning applies to most types of CPAP or bilevel devices.
- The technical specifications of the mask are provided for your clinician to check that they are compatible with the CPAP or bilevel device. If used outside specification or if used with incompatible devices, the seal and comfort of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect the CPAP or bilevel device function.
- Discontinue using this mask if you have ANY adverse reaction to the use of the mask, and consult your physician or sleep therapist.
- Using a mask may cause tooth, gum or jaw soreness or aggravate an existing dental condition. If symptoms occur, consult your physician or dentist.
- The F20 line of full face CPAP masks are not intended to be used simultaneously with nebulizer medications that are in the air path of the mask/tube.
- As with all masks, some rebreathing may occur at low CPAP pressures.
- Refer to your CPAP or bilevel device manual for details on settings and operational information.
- Remove all packaging before using the mask.

Using your mask

When using your mask with ResMed CPAP or bilevel devices that have mask setting options, refer to the Technical specifications section in this user guide for the correct setting.

For a full list of compatible devices for this mask, see the Mask/Device Compatibility List on www.resmed.com/downloads/masks. If you do not have internet access, please contact your ResMed representative.

Use a standard conical connector if pressure readings and/or supplemental oxygen are required.

Fitting

1. Twist and pull both magnetic clips away from the frame.
2. Ensure that the ResMed logo on the headgear is facing outwards and is upright. With both lower headgear straps released, hold the mask against your face and pull the headgear over your head.
3. Bring the lower straps below your ears, and attach the magnetic clip to the frame.
4. Undo the fastening tabs on the upper headgear straps. Pull the straps evenly until the mask is stable and positioned as shown in the illustration. Reattach the fastening tabs.
5. Undo the fastening tabs on the lower headgear straps. Pull the straps evenly until the mask is stable and sits comfortably on the chin. Reattach the fastening tabs.
6. Connect the device air tubing to the elbow. Attach the elbow to the mask by pressing the side buttons and pushing the elbow into the mask, ensuring it clicks in on both sides.
7. Your mask and headgear should be positioned as shown in the illustration.

Adjustment (AirFit F20)

If necessary, slightly adjust the position of the mask for the most comfortable fit. Ensure that the cushion is not creased and the headgear is not twisted.

1. Turn on your device so that it is blowing air.

Adjustment tips:

- ✓ With air pressure applied, pull the mask away from your face to allow the cushion to inflate and reposition onto your face.

- ✓ To resolve any leaks at the upper part of the mask, adjust the upper headgear straps. For the lower part, adjust the lower headgear straps.
- ✓ Adjust only enough for a comfortable seal. Do not overtighten as this may cause discomfort.

Adjustment (AirTouch F20)

If necessary, slightly adjust the position of the mask for the most comfortable fit. Ensure that the headgear is not twisted.

1. Turn on your device so that it is blowing air.

Adjustment tips:

- ✓ To resolve any leaks at the upper part of the mask, adjust the upper headgear straps. For the lower part, adjust the lower headgear straps.
- ✓ Adjust enough for a comfortable seal.

Removal

1. Twist and pull both magnetic clips away from the frame.
2. Pull the mask away from your face and back over your head.

Disassembly

If the mask is connected to your device, disconnect the device air tubing from the elbow.

1. Undo the fastening tabs on the upper headgear straps. Pull the straps out of the frame.

Tip: Keep the magnetic clips attached to the lower headgear straps to easily distinguish the upper and lower straps when reassembling.

2. Remove the elbow from the mask by pressing the side buttons and pulling the elbow away.
3. Hold the side of the frame between the upper and lower arms. Gently pull the cushion away from the frame.

Reassembly

1. Attach the cushion to the frame by aligning the circular openings and pushing together until retained.

2. With the ResMed logo on the headgear facing outside and upright, thread the upper headgear straps into the frame slots from the inside. Fold them over to secure.

Cleaning your mask at home (AirFit F20)

Handwash your mask and headgear by gently rubbing in warm (approximately 86°F/30°C) water using mild liquid detergent. Rinse all components well under running water and allow to air dry out of direct sunlight.

WARNING

- As part of good hygiene, always follow cleaning instructions and use a mild liquid detergent. Some cleaning products may damage the mask, its parts and their function, or leave harmful residual vapours that could be inhaled if not rinsed thoroughly.
- Regularly clean your mask and its components to maintain the quality of your mask and to prevent the growth of germs that can adversely affect your health.

CAUTION

Visible criteria for product inspection: If any visible deterioration of a system component is apparent (cracking, discoloration, tears etc.), the component should be discarded and replaced.

Daily/After each use:

1. Disassemble the mask according to the disassembly instructions.
2. Rinse the frame, elbow and cushion under running water. Clean with a soft brush until dirt is removed.
3. Soak the components in warm water with a mild liquid detergent for up to ten minutes.
4. Shake the components in the water.
5. Brush the moving parts of the elbow and around the vent holes.
6. Brush the areas of the frame where the arms connect, and inside and outside the frame where the elbow connects.
7. Rinse the components under running water.
8. Leave the components to air dry out of direct sunlight. Make sure to squeeze the arms of the frame to ensure that excess water is removed.

Weekly:

1. Disassemble the mask. The magnets can remain attached to the headgear during cleaning.
2. Handwash the headgear in warm water with mild liquid detergent.
3. Rinse the headgear under running water. Inspect to ensure the headgear is clean and detergent free. Wash and rinse again, if necessary.
4. Squeeze the headgear to remove excess water.
5. Leave the headgear to air dry out of direct sunlight.

Cleaning your mask at home (AirTouch F20)

Handwash the elbow, frame and headgear (not the cushion) by gently rubbing in warm (approximately 86°F/30°C) water using mild liquid detergent. Rinse them well under running water and allow to air dry out of direct sunlight.

If required, it is recommended to wipe the cushion using CPAP wipes or equivalent and allow to dry. It is recommended to replace your cushion every month.

WARNING

- As part of good hygiene, always follow cleaning instructions (using mild liquid detergent for recommended components and if required, wiping the cushion with CPAP wipes or equivalent). Some cleaning products may damage the mask, its parts and their function, or leave harmful residual vapors that could be inhaled if not rinsed thoroughly.
- Regularly clean your mask and its components to maintain the quality of your mask and to prevent the growth of germs that can adversely affect your health.

CAUTION

- Visible criteria for product inspection: If any visible deterioration of a system component is apparent (cracking, discoloration, tears, etc.), the component should be discarded and replaced.
- The cushion must not be submerged in liquid as this may damage the cushion and affect mask performance.
- Discard the cushion if it is submerged in liquid or heavily soiled.

Daily/After each use:

1. Disassemble the mask according to the disassembly instructions.
2. If required, wipe your cushion with a CPAP wipe or equivalent and then allow to dry. Important – do not get cushion wet.
3. Rinse the frame and elbow under running water. Clean with a soft brush until dirt is removed.
4. Soak the components in warm water with a mild liquid detergent for up to ten minutes.
5. Shake the components in the water.
6. Brush the moving parts of the elbow and around the vent holes.
7. Brush the areas of the frame where the arms connect, and inside and outside the frame where the elbow connects.
8. Rinse the components under running water.
9. Leave the components to air dry out of direct sunlight. Make sure to squeeze the arms of the frame to ensure that excess water is removed.

Weekly:

1. Disassemble the mask. The magnets can remain attached to the headgear during cleaning.
2. Handwash the headgear in warm water with mild liquid detergent.
3. Rinse the headgear under running water. Inspect to ensure the headgear is clean and detergent free. Wash and rinse again, if necessary.
4. Squeeze the headgear to remove excess water.
5. Leave the headgear to air dry out of direct sunlight.

Monthly:

Replace the cushion by following relevant steps of the disassembly / reassembly instructions.

Reprocessing the mask between patients

Reprocess this mask when using between patients. Cleaning, disinfection and sterilization instructions are available on www.resmed.com/downloads/masks. If you do not have internet access, please contact your ResMed representative.

Troubleshooting (AirFit F20)

Problem/possible cause	Solution
Mask is uncomfortable. Headgear straps are too tight.	The cushion membrane is designed to inflate against your face to provide a comfortable seal with low headgear tension. Adjust straps evenly. Ensure that the headgear straps are not too tight and that the cushion is not creased.
Mask could be the wrong size.	Talk to your clinician to have your face size checked against F20 fitting template. Note that sizing across different masks is not always the same.
Mask is too noisy. Elbow incorrectly installed or incorrect assembly of the mask system.	Remove the elbow from your mask, then reassemble according to the instructions. Check that the mask is correctly assembled according to the instructions.
Vent is dirty.	Use a soft bristle brush to clean the vent.
Mask leaks around the face. Cushion membrane is creased. Mask is incorrectly positioned or adjusted.	Refit your mask according to the instructions. Ensure that you position the cushion correctly on your face before pulling headgear over your head. Do not slide the mask down your face during fitting as this may lead to creasing of the cushion.
Mask could be the wrong size.	Talk to your clinician to have your face size checked against fitting template. Note that sizing across different masks is not always the same.

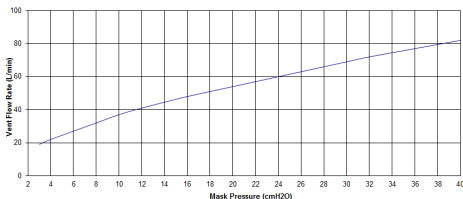
Troubleshooting (AirTouch F20)

Problem/possible cause	Solution
Mask is uncomfortable.	
Headgear straps are too tight.	Adjust straps evenly. Ensure that the headgear straps are not too tight.
Mask could be the wrong size.	Talk to your clinician to have your face size checked against F20 fitting template. Note that sizing across different masks is not always the same.
Mask is too noisy.	
Elbow incorrectly installed.	Remove the elbow from your mask, then reassemble according to the instructions.
Vent is dirty.	Use a soft bristle brush to clean the vent.
Mask leaks around the face.	
Headgear straps are too loose.	Tighten the straps evenly until you have a comfortable seal.
Cushioned is not positioned correctly.	Reposition mask on your face. If leak continues, turn off device, resettle your cushion and then turn device back on.
Cushion is nearing the end of its life.	The cushion is designed to be replaced on a monthly basis. Cushion performance may deteriorate as it nears the end of its life. Adjust your headgear and if the problem persists, replace the cushion.
Mask could be the wrong size.	Talk to your clinician to have your face size checked against fitting template. Note that sizing across different masks is not always the same.

Technical specifications

Pressure-flow curve

The mask contains passive venting to protect against rebreathing. As a result of manufacturing variations, the vent flow rate may vary.



Pressure (cm H ₂ O)	Flow (L/min)
3	19
10	37
16	48
24	60
30	69
40	82

	AirFit F20	AirTouch F20
Dead space: Empty volume of the mask to the end of the swivel. The mask deadspace varies according to cushion size.	240 mL (Large)	281 mL (Large)
Therapy pressure	3 to 40 cm H ₂ O	3 to 40 cm H ₂ O
Resistance with Anti Asphyxia Valve (AAV) closed to atmosphere: Drop in pressure measured (nominal)		
at 50 L/min	0.2 cm H ₂ O	0.2 cm H ₂ O
at 100 L/min	0.6 cm H ₂ O	0.6 cm H ₂ O
Resistance with Anti Asphyxia Valve (AAV) open to atmosphere		
Inspiration at 50 L/min:	0.6 cm H ₂ O	0.6 cm H ₂ O
Expiration at 50 L/min:	0.7 cm H ₂ O	0.7 cm H ₂ O
Anti Asphyxia Valve (AAV) open-to-atmosphere pressure	≤3 cm H ₂ O	≤3 cm H ₂ O
Anti Asphyxia Valve (AAV) closed-to-atmosphere pressure	≤3 cm H ₂ O	≤3 cm H ₂ O
Sound: DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level and the A-weighted sound pressure level of the mask at a distance of 1 m, with uncertainty of 3 dBA, are shown		
Power level	30 dBA	30 dBA
Pressure level	23 dBA	23 dBA

Environmental conditions	Operating temperature: 41°F to 104°F (5°C to 40°C) Operating humidity: 15% to 95% non-condensing Storage and transport temperature: -4°F to 140°F (-20°C to +60°C) Storage and transport humidity: up to 95% non-condensing
Gross dimensions	Mask fully assembled with elbow assembly (no headgear) 6.1" (H) x 6.3" (W) x 5.8" (D) (154 mm (H) x 159 mm (W) x 147 mm (D))
International Commission on Non-Ionizing Radiation Protection (ICNIRP)	Magnets used in this mask are within ICNIRP guidelines for general public use.
Service life	The service life of the F20 mask system is dependent on the intensity of usage, maintenance, and environmental conditions to which the mask is used or stored. As this mask system and its components are modular in nature, it is recommended that the user maintain and inspect it on a regular basis, and replace the mask system or any components if deemed necessary or according to the 'visual criteria for product inspection' in the 'Cleaning your mask at home' section of this guide. Refer to the 'Mask components' section of this guide for information of how to order replacement parts.
Mask setting options	For AirSense, AirCurve or S9: Select 'Full Face'. For other devices: Select 'MIR FULL' (if available), otherwise select 'FULL FACE' as the mask option.



Device Setting

Full Face

Notes:

- This product is not made with PVC or phthalates such as DEHP, DBP or BBP.
- This product is not made with natural rubber latex.
- The manufacturer reserves the right to change these specifications without notice.

Storage















Ensure that the mask is thoroughly clean and dry before storing it for any length of time. Store the mask in a dry place out of direct sunlight.

Disposal

This mask does not contain any hazardous substances and may be disposed of with your normal household refuse.

Symbols

The following symbols may appear on your product or packaging:

	Catalog number		Batch code
	Humidity limitation		Temperature limitation
	Fragile, handle with care		Not made with natural rubber latex
	Manufacturer		European Authorized Representative
	Keep away from rain		This way up
	Full face mask		Device setting - Full Face
	Size - small		Size - medium



Size - large



Indicates a Warning or Caution and alerts you to a possible injury or explains special measures for the safe and effective use of the device



Caution, consult accompanying documents



Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician)

Limited warranty

ResMed Ltd (ResMed) warrants that your ResMed mask system (including mask frame, cushion, headgear and tubing) will be free from defects in material and workmanship from the date of purchase for 90 days, or in the case of disposable masks and disposable mask components for 7 days. This warranty is only available to the initial consumer. It is not transferable. If the product fails under conditions of normal use, ResMed will repair or replace, at its option, the defective product or any of its components. This limited warranty does not cover: a) any damage caused as a result of improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by ResMed to perform such repairs; and c) any damage or contamination due to cigarette, pipe, cigar or other smoke. Warranty is void on product sold, or resold, outside the region of original purchase.

Warranty claims on defective product must be made by the initial consumer at the point of purchase.

This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

ResMed will not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any ResMed product. Some regions or states do not allow the exclusion or

limitation of incidental or consequential damages, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from region to region. For further information on your warranty rights, contact your local ResMed dealer or ResMed office.

Mask components / Composants du masque /
Piezas de la mascarilla / Componentes da máscara

		AirFit F20 / AirTouch F20	AirFit F20 for Her / AirTouch F20 for Her
A	Elbow / Coude / Codo / Cotovelo	—	—
1	Valve (AAV) / Valve (VAA) / Válvula (AAV) / Válvula (VAA)		
2	Vent / Orifice de ventilation / Ventilación / Respiradouro		
3	Side buttons / Boutons latéraux / Botones laterales / Botões laterais		
4	Swivel / Pièce pivotante / Pieza giratoria / Peça giratória		
B	Frame / Entourage rigide / Armazón / Armação	—	—
C	AirFit F20 – Cushion / Bulle / Almohadilla / Almofada	63467 (S) 63468 (M) 63469 (L)	63467 (S) 63468 (M) 63469 (L)
	AirTouch F20 – Cushion / Bulle / Almohadilla / Almofada	63028 (S) 63029 (M) 63030 (L)	63028 (S) 63029 (M) 63030 (L)
D	Headgear / Harnais / Arnés / Arnês	63470 (S) 63471 (M) 63472 (L)	63473 (Std)
5	Magnetic clips / Clips magnétiques / Broches magnéticos / Presilhas magnéticas		
6	Lower headgear straps Sangles inférieures du harnais / Correas inferiores del arnés / Correias inferiores do arnês		

		AirFit F20 / AirTouch F20	AirFit F20 for Her / AirTouch F20 for Her
7	Upper headgear straps / Sangles supérieures du harnais / Correas superiores del arnés / Correias superiores do arnês		
A+B+C			
	AirFit F20 – Frame system / Entourage complet / Sistema de armazón / Sistema de armação	63460 (S) 63461 (M) 63462 (L)	63463 (S) 63464 (M)
	AirTouch F20 – Frame system / Entourage complet / Sistema de armazón / Sistema de armação	63021 (S) 63022 (M) 63023 (L)	63024 (S) 63025 (M)
A+B+C+D			
	AirFit F20 – Complete system / Masque complet / Sistema completo / Sistema completo	63400 (S) 63401 (M) 63402 (L)	63403 (S) 63404 (M)
	AirTouch F20 – Complete system / Masque complet / Sistema completo / Sistema completo	63000 (S) 63001 (M) 63002 (L)	63003 (S) 63004 (M)

S: Small / Small / Pequeña / Pequeno

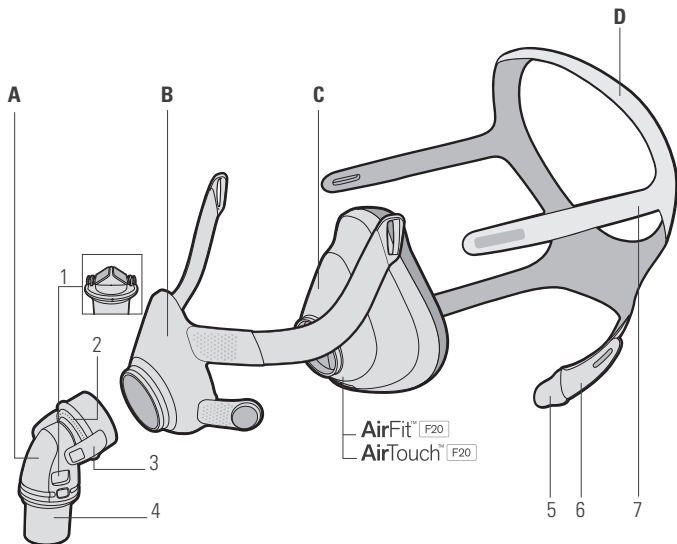
M: Medium / Medium / Mediana / Médio

L: Large / Large / Grande / Grande

Std: Standard / Standard / Estándar / Padrão



AirFit™ F20
AirTouch™ F20



ResMed Ltd
1 Elizabeth Macarthur
Drive Bella Vista NSW
2153 Australia

Distributed by
ResMed Corp 9001 Spectrum Center Boulevard San Diego
CA 92123 USA **EC REP** ResMed (UK) Ltd 96 Jubilee Ave Milton Park
Abingdon Oxfordshire OX14 4RW UK

See ResMed.com for other ResMed locations worldwide. AirFit, AirTouch, AirSense and AirCurve are trademarks and/or registered trademarks of the ResMed family of companies. For patent and other intellectual property information, see ResMed.com/ip. © 2016 ResMed Ltd. 638091/1 2016-11

ResMed.com



638091



Urgent Field Safety Notice

ResMed Masks with Magnets - Potential Magnetic Interference with Certain Medical Devices

PATIENT LETTER

Reference: MWM-2023-FSN-01

Date: 20 November 2023

Dear Patient,

ResMed is providing you with important information regarding our masks with magnets, which may interact with some implants or certain medical devices. It is important that you understand the information contained in this letter, take action if necessary, and keep it for future reference.

In response to new information from latest industry practices and global safety data, ResMed is **updating the Contraindications and Warnings** in our User Guides to instruct patients on the safe use of **ResMed masks with magnets**.

- Contraindications: conditions under which the mask is not to be used.
- Warnings: identify a possible hazard and provide information on how to safely use the mask.

General Product Description

These masks are used to deliver air to a patient from a positive airway pressure (PAP) device.

Magnets are used in some ResMed masks to provide a simple and easy way for patients to attach and detach the headgear to the mask frame when regularly fitting the mask for use. This can be notably beneficial to patients with disabilities, including those facing dexterity or vision impairment.

Which masks are affected?

The following ResMed masks contain magnets, please note that mask availability may differ in each country. If you do not use one of the masks identified below, this letter does not apply to you.

Mask type	Affected masks
Full face mask	AirFit F20, AirFit F20 for Her AirTouch F20, AirTouch F20 for Her AirFit F30 AirFit F30i
Nasal mask	AirFit N10, AirFit N10 for Her AirFit N20, AirFit N20 for Her AirTouch N20, AirTouch N20 for Her
Non vented mask	AirFit F20 NV

See **Appendix A** for more information on identifying your ResMed mask and the specific location of the magnets.



What has changed?

ResMed is updating the **Contraindications** and **Warning** relating to magnetic interference, in its User Guides for all masks with magnets.

Updated Contraindications

Masks with magnetic components are contraindicated for use by patients where they, or anyone in close physical contact while using the mask, have the following:

- Active medical implants that interact with magnets (i.e., pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, cerebrospinal fluid (CSF) shunts, insulin/infusion pumps)
- Metallic implants/objects containing ferromagnetic material (i.e., aneurysm clips/flow disruption devices, embolic coils, stents, valves, electrodes, implants to restore hearing or balance with implanted magnets, ocular implants, metallic splinters in the eye)

Updated Warning

Keep the mask magnets at a safe distance of at least 6 inches (150 mm) away from implants or medical devices that may be adversely affected by magnetic interference. This warning applies to you or anyone in close physical contact with your mask. The magnets are in the frame and lower headgear clips, with a magnetic field strength of up to 400mT. When worn, they connect to secure the mask but may inadvertently detach while asleep.

Implants/medical devices, including those listed within contraindications, may be adversely affected if they change function under external magnetic fields or contain ferromagnetic materials that attract/repel to magnetic fields (some metallic implants, e.g., contact lenses with metal, dental implants, metallic cranial plates, screws, burr hole covers, and bone substitute devices). Consult your physician and manufacturer of your implant / other medical device for information on the potential adverse effects of magnetic fields.

Patient Safety Information

ResMed's masks with magnets are safe when used in accordance with the updated Instructions for Use including the **Contraindications** and **Warnings**.

When a magnet comes close to certain medical implants/devices (less than 6 inches / 150mm) there is potential for magnetic interference to change:

- the function of an implant/medical device
- the position of implants made of ferromagnetic material

In rare circumstances, this can lead to serious injury or death.

Contraindicated patients can avoid the potential harm from magnetic interference by using an alternative mask without magnets. All other patients using ResMed masks with magnets can continue to use the mask following the updated Instructions for Use.

From 2014 to November 2023, ResMed has sold tens of millions of masks with magnets globally. In this time, ResMed has submitted five (5) reports of serious harm (medical intervention /hospitalization) that were potentially related to magnetic interference with an implanted device (including implantable cardioverter defibrillators (ICD) and cerebrospinal fluid (CSF) shunts) to relevant Regulatory Authorities. No permanent injuries or deaths have been reported.



Actions to be taken by you

Contraindicated patients using a ResMed mask with magnets

If you, or anyone in close physical contact while using the mask (e.g. bed partner), have an active medical implant or metallic implanted object that is identified within the **Contraindications** above:

- Replace your mask containing magnets with an alternative mask without magnets in a timely manner. Contact your mask provider for alternative mask options.
Note, ResMed is making our masks without magnets available to your mask provider for replacement.
- If an alternative mask is not available, consult your physician/doctor for appropriate next steps regarding your therapy.
- Dispose of the mask with magnets after you receive an alternative mask.

Note, not all models or variants of medical devices listed in the contraindications are affected by external magnetic fields. If you are not sure whether a medical device/implant falls under the Contraindications, or you require additional information on the potential adverse effects of magnetic fields for your particular device, please contact your physician/doctor.

All other patients using a ResMed mask with magnets

If you are NOT contraindicated from using a ResMed mask with magnets, you may continue to use the mask, ensuring you follow all user instructions, including the updates described in this letter.

- Importantly, ResMed masks with magnets are to be kept at least 6 inches (150mm) away from implants or medical devices that may be adversely affected by magnetic interference, as described in the updated **Warning**.

For more information regarding these changes please visit www.resmed.com/magnetupdate.

Reporting an Adverse Event

If you have experienced an adverse event related to the use of ResMed masks with magnets, please visit www.resmed.com/contact or contact your mask provider. Alternatively, adverse events experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either [online](#), or by regular mail or by fax. 1-800-332-1088 to request a form.

Manufacturer

ResMed Pty Ltd
1 Elizabeth Macarthur Drive
Bella Vista 2153
Australia

We appreciate your support and consider this action necessary to ensure that all patients are aware of these updates. If you have any questions or concerns or would like more information, please contact your mask provider or physician/doctor.

Sincerely,

A handwritten signature in black ink, appearing to read "Dawn Y. Haake".




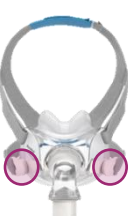




Dawn Y. Haake
Chief Quality Officer

APPENDIX A - RESMED MASKS WITH MAGNETS

Note, product availability may differ in each country.

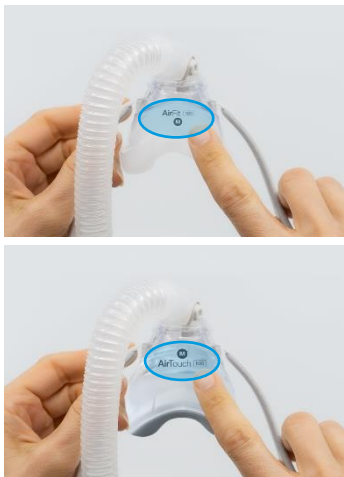





Magnet
locations

Products Affected	Location of Model Name	Location of Magnets
AirFit™ F30i		
AirFit™ F30 Full face mask		
AirFit™ F20 Full face mask AirFit™ F20 Full face mask for Her AirTouch™ F20 Full face mask AirTouch™ F20 Full face mask for Her	 	 

APPENDIX A - RESMED MASKS WITH MAGNETS (CONTINUED)

Note, product availability may differ in each country.

Products Affected	Location of Model Name	Location of Magnets
AirFit™ N20 Nasal mask AirFit™ N20 Nasal mask for Her AirTouch™ N20 Nasal mask AirTouch™ N20 Nasal mask for Her		
AirFit™ F20 NV		
AirFit™ N10 Nasal mask AirFit™ N10 Nasal mask for Her	