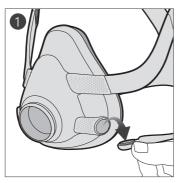


User guide English

### Fitting

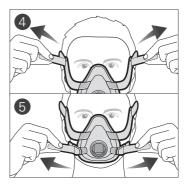






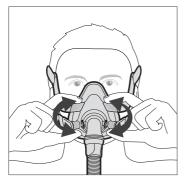


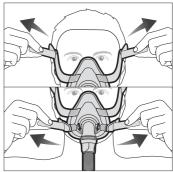






### Adjustment



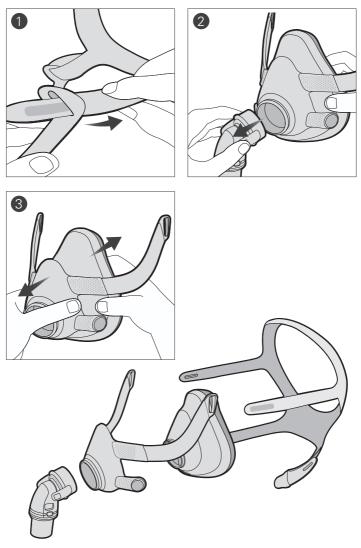


Removal

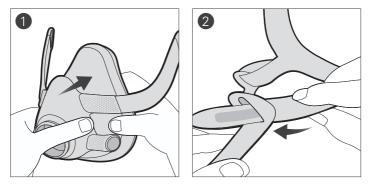


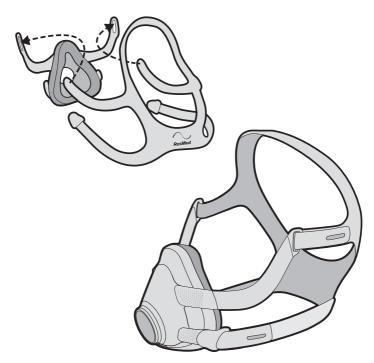


### Disassembly



### Reassembly





### Cleaning the vent





# **Air**Fit<sup>™</sup> F20

## AirTouch<sup>™</sup> [F20]

Full face mask

Thank you for choosing the AirFit<sup>™</sup> F20/AirTouch<sup>™</sup> 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<sup>™</sup> F20/AirFit<sup>™</sup> F20 for Her
- AirTouch<sup>™</sup> F20/AirTouch<sup>™</sup> 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 multipatient 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.
- 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.
- 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)

It is important to follow the steps below to get the best performance out of your mask.

## ▲ 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.

## $\triangle$ 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 (approximately 86°F/30°C) 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 (approximately 86°F/30°C) 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)

It is important to follow the steps below to get the best performance out of your mask. It is recommended to replace your cushion every month.

## ▲ WARNING

- As part of good hygiene, always follow cleaning instructions. 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.

## $\triangle$ 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.

#### Cleaning the cushion

You do not need to clean the cushion every day. If any visible deterioration of the cushion is apparent, the cushion should be discarded and replaced.

- If required, wipe the outside of the foam cushion with CPAP wipes or similar alcohol-free wipes and allow to dry.
- Do not rinse or submerge in liquid
- Do not expose to domestic cleaning products or cleaning devices
- Do not store or place in direct sunlight.

#### Cleaning the frame and elbow

#### Daily:

- 1. Disassemble the mask components according to the disassembly instructions.
- 2. Rinse the frame and elbow under running water.
- 3. Clean with a soft brush until dirt is removed.
- 4. Soak the components in warm water (approximately 86°F/30°C) with a mild liquid detergent for up to ten minutes.
- 5. Shake the components in the water.
- 6. Brush the moving part 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 excess water is removed.

#### Cleaning the headgear

#### Weekly:

- 1. Disassemble the mask. The magnets can remain attached to the headgear during cleaning.
- 2. Handwash the headgear in warm water (approximately 86°F/30°C) 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.

## 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.	Repostion 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.	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 pas		
	rebreathing. As a resu	It of manufacturin	ig variations, the vent
	flow rate may vary.		Pressure Flow
100			$(cm H_2O)$ (L/min)
80			3 19
Ē			10 37
w Rate			16 48
Vert Flow Rate (Umin)			24 60
\$20			30 69
			40 82
2 4 6 8 10 12 14	16 18 20 22 24 26 28 30 Mask Pressure (cm H <sub>2</sub> O)	32 34 36 38 40	
		AirFit F20	AirTouch F20
Dead space: Empty volu		240 mL (Large)	281 mL (Large)
end of the swivel. The ma			
according to cushion size			
Therapy pressure		3 to 40 cm H <sub>2</sub> O	3 to 40 cm H <sub>2</sub> O
Resistance with Anti A			
closed to atmosphere: measured (nominal)	Drop in pressure		
at 50 L/min		0.2 cm H <sub>2</sub> O	0.2 cm H <sub>2</sub> O
at 100 L/min		0.6 cm H <sub>2</sub> O	0.6 cm H <sub>2</sub> O
Resistance with Anti A	sphyxia Valve (AAV)	0.0 0111120	0.0 011120
open to atmosphere			
Inspiration at 50 L/min:		0.6 cm H <sub>2</sub> O	0.6 cm H <sub>2</sub> O
Expiration at 50 L/min:		0.7 cm H <sub>2</sub> O	0.7 cm H <sub>2</sub> O
Anti Asphyxia Valve (A	AV) open-to-	≤3 cm H <sub>2</sub> O	≤3 cm H₂0
atmosphere pressure			
Anti Asphyxia Valve (A	AV) closed-to-	$\leq$ 3 cm H <sub>2</sub> O	$\leq$ 3 cm H <sub>2</sub> O
atmosphere pressure			
Sound: DECLARED DUAL			
ISO 4871. The A-weighte			
the mask at a distance of Power level	I m, with uncertainty o		vn 30 dBA
Power level Pressure level		30 dBA 23 dBA	30 dBA 23 dBA
11033010 10701		20 UDA	23 UDA

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) 6.06" (H) x 6.26" (W) x 5.79" (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:

DEE		LOT		
CATALOG NUMBER	Catalog number	BATCH	Batch code	
HUMIDITY LIMITATION	Humidity limitation	-20°C -4°F TEMPERATURE LINITATION	Temperature limitation	
FRAGILE HANDLE HANDLE	Fragile, handle with care	NOT MADE	Not made with natural rubber latex	
WANUFACTURER	Manufacturer	ECREP	European Authorized Representative	
KEEP DRY	Keep away from rain	THIS WAY UP	This way up	
Full Face Mask	Full face mask	Device Betting Full Faced	Device setting - Full Face	
S	Size - small	M	Size - medium	
0	Size - large			
$\wedge$	Indicates a Warning or Cautio special measures for the safe		you to a possible injury or explains e use of the device	



#### Caution, consult accompanying documents

DO NOT USE IF PACKAGE IS DANAGED	Do not use if package damaged	SINGLE PATIENT RELESE	Single patient reuse
	Discard once signs of deterioration forms	¥	Do not expose to direct sunlight
<b>i</b>	Replace once signs of deterioration forms		Do not use domestic cleaner or domestic cleaning devices
STA	Clean with alcohol-free wipes only	1	Do not use alcohol wipes
<b>1</b>	Keep dry and away from liquids	No.	Do not submerge in liquids
$R_{\!\!X^{\text{Only}}}$	Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician.)		

## Limited warranty

ResMed Pty Ltd (hereafter '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. During the warranty period, 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; c) any damage or contamination due to cigarette, pipe, cigar or other smoke; and d) any damage caused by exposure to ozone, activated oxygen or other gases. 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 shall 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.

Visit ResMed.com for the latest information on ResMed's Limited Warranty.

#### Mask components

		AirFit F20 / AirTouch F20	AirFit F20 for Her / AirTouch F20 for Her
Α	Elbow	—	—
1	Valve (AAV)		
2	Vent		
3	Side buttons		
4	Swivel		
В	Frame	—	_
C	AirFit F20 – Cushion	63467 (S) 63468 (M) 63469 (L)	63467 (S) 63468 (M) 63469 (L)
	AirTouch F20 – Cushion	63028 (S) 63029 (M) 63030 (L)	63028 (S) 63029 (M) 63030 (L)
D	Headgear	63470 (S) 63471 (M) 63472 (L)	63473 (Std)
5	Magnetic clips		
6	Lower headgear straps		
7	Upper headgear straps		
A+E	3+C		
	AirFit F20 – Frame system	63460 (S) 63461 (M) 63462 (L)	63463 (S) 63464 (M)

	AirFit F20 / AirTouch F20	AirFit F20 for Her / AirTouch F20 for Her
AirTouch F20 – Frame system	63021 (S) 63022 (M) 63023 (L)	63024 (S) 63024 (M)
A+B+C+D		
AirFit F20 – Complete system	63400 (S) 63401 (M) 63402 (L)	63403 (S) 63404 (M)
AirTouch F20 – Complete system	63000 (S) 63001 (M) 63002 (L)	63003 (S) 63004 (M)

S: Small

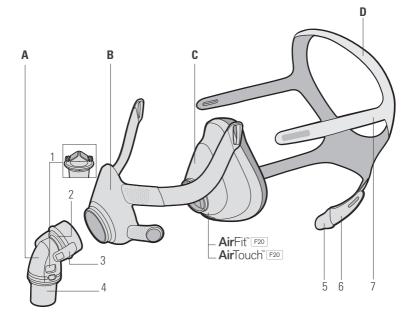
M: Medium

L: Large

Std: Standard







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