

PHILIPS

RESPIRONICS

DreamWear

Full Face Mask

Instructions for use – **EN**

1 Safety Information

Intended Use

This mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP therapy or bi-level therapy has been prescribed.

⚠ Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

⊖ Note: This mask is not made with natural rubber latex or DEHP.

Contraindications

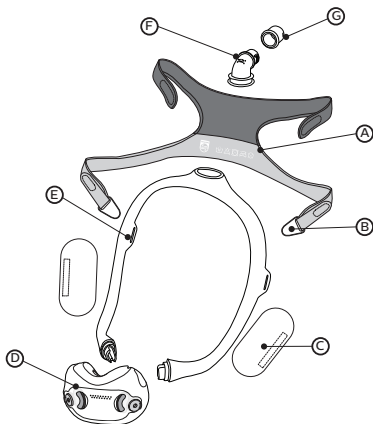
This mask is not for use on patients with the following conditions: recent eye surgery or dry eyes, hiatal hernia, excessive reflux, impaired cough reflex, and impaired cardiac sphincter function. This mask is not for use on patients who are dependent on mechanical ventilation for their life support. This mask is not for use on patients who are taking a prescription drug that induces vomiting, or on patients who are uncooperative, unresponsive or unable to remove the mask by themselves.

⚠ Warnings

- Use of this mask while the system is not on and operating may cause rebreathing of exhaled air. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.

- Discontinue use and contact your healthcare professional if any of the following symptoms occur: skin redness, irritation, discomfort, blurred vision, or drying of the eyes.
- Discontinue use and consult your healthcare professional if any of the following symptoms occur: unusual chest discomfort, shortness of breath, severe headache, eye pain or eye infections.
- Discontinue use and consult your healthcare professional if any of the following symptoms occur: tooth, gum, or jaw soreness. Use of a mask may aggravate an existing dental condition.
- A minimum of 3 cm H₂O (hPa) must be maintained when using this mask.
- Do not overtighten the headgear straps. Watch for signs of overtightening, such as excessive redness, sores or bulging skin around the edges of the mask. Loosen the headgear straps to alleviate symptoms.
- The headgear clips and mask cushion contain magnets. Contact your healthcare provider before you use this mask. Some medical devices may be affected by magnetic fields. The magnetic clips in this mask should be kept at least 2 in. (50 mm) away from any active medical device with special attention to implanted devices such as pacemakers, defibrillators and cochlear implants.
- Do not use in or near magnetic resonance imaging (MRI) equipment.
- Do not block or seal the holes and exhalation ports.

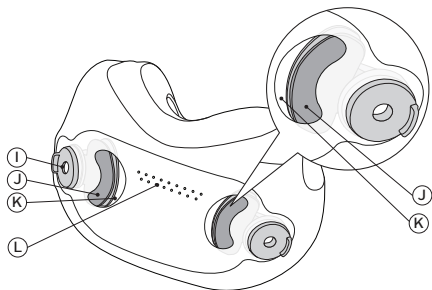
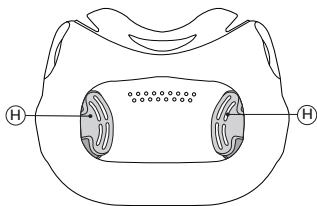
2 What's in the Package



- (A) Headgear
- (B) Magnetic headgear clip
- (C) Mask frame fabric sleeves (optional)
- (D) Mask cushion (available in S, M, L, MW)
- (E) Mask frame (available in small (SM), medium (MED), large (LG))
- (F) Elbow with built-in exhalation (do not block)
- (G) Tubing quick release (may remain in the CPAP hose)

Back of the Cushion

Front of the Cushion



- Ⓜ Guards
- Ⓜ Magnetic Clips
- Ⓜ Flaps
- Ⓜ Large Holes (Two) in the Cushion (do not block)
- Ⓜ Small Holes in the Cushion (do not block)

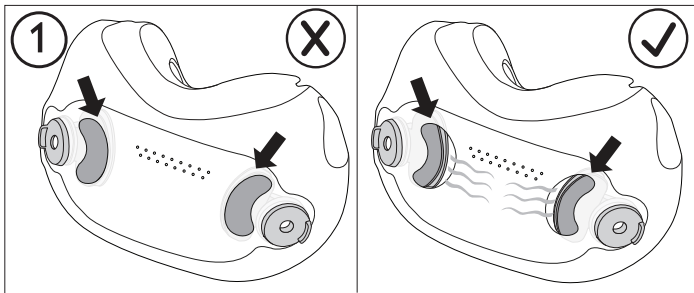
3 Before Use

DAILY BEFORE USE VERIFY FOR SAFETY

1. Look at the front of your mask cushion.
2. Find the two large holes.
3. Find the flaps. The flaps are clear, thin pieces that sit on the guards behind the holes.
4. Do not use if the two large holes are blocked shut by the flaps or anything else (for example, mucus). ①

⚠ Warning: Do not block any of the mask holes.

⊖ Note: The flaps should cover the two large holes when the device is on.



Before Use Read and Understand the Instructions Completely.

- Hand wash the entire mask before use (see **Mask Care** section).
- Wash your face. Do not use moisturizer or lotion on your hands or face.
- Inspect the entire mask daily. Discard and replace any damaged or worn parts.

4 Achieving the Right Fit

Cushion Sizing

Four cushion sizes (S, M, L, MW) are available. Place the cushion sizing gauge under your nose (as shown).

*** Tip:** For the best performance, use the smallest cushion that fits your nose.

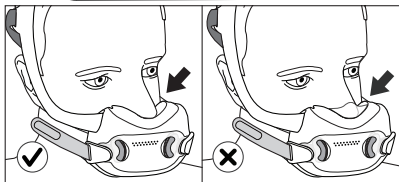
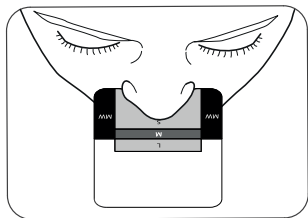
1. Hold the gauge horizontally under your nose and select the cushion size based on where the outer edge of your nostrils and tip of your nose contact the gauge. A mirror or another person may assist with sizing.

2. The cushion opening will be directly under your nostrils. The cushion will hug your nose and mouth, and leak will be minimal.
3. At no time should your nose be inside of the cushion opening. If any part of the cushion overlaps your nose, the cushion is being worn incorrectly. A different size cushion may be needed.

Contact your healthcare provider for additional information.

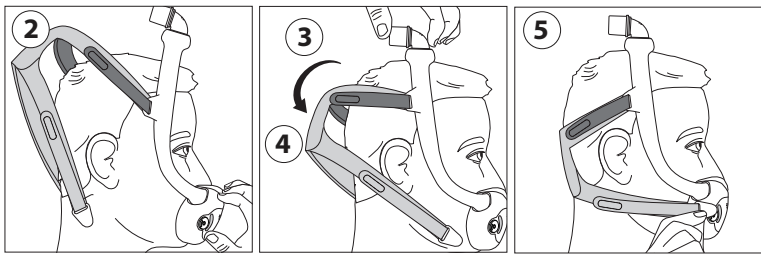
Philips Respironics DreamStation Mask Type and System One Resistance Control Settings

Using your mask with a Philips Respironics DreamStation or System One device provides optimal comfort. The provider sets this value (X1) on your device.



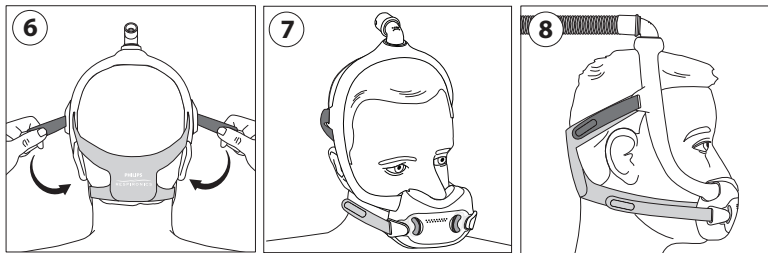
Putting on the Mask

1. With the mask assembled (see **Assembly** section), place the cushion under the nose. ②
2. Position the frame on the top of your head. ③
- ❖ **Tip:** For proper sizing, see **Cushion Sizing** and **Mask Frame Selection** sections.
3. Pull the headgear over the back of the head. ④
4. Attach the magnetic headgear clips to the mask cushion. ⑤



Adjusting the Mask

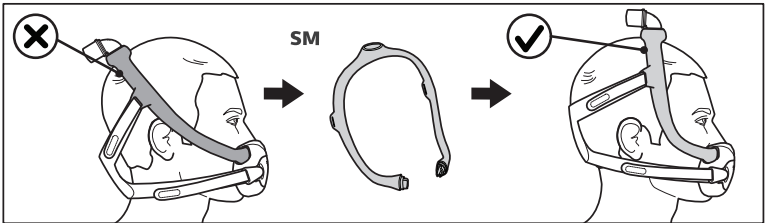
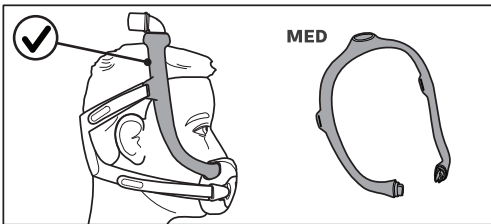
1. Peel the headgear tabs away from the fabric. Adjust the length of the top straps. Press the tabs back against the fabric to reattach. Repeat this step with the bottom straps. ⑥
- ⊖ **Note:** Do not overtighten the headgear. Signs of overtightening include redness, sores, or bulging skin around the edges of the mask.
2. Position the mask until it fits comfortably. ⑦
3. When finished the elbow should rest at the top of the head. ⑧



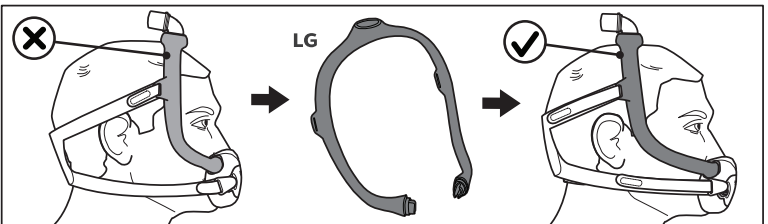
Mask Frame Sizing

- Medium (MED) frame
- Small (SM) frame
- Large (LG) frame

The medium (MED) mask frame will comfortably fit most faces. If the MED frame does not fit your face, contact your healthcare provider to see if a small (SM) or large (LG) mask frame would better suit your needs.



✿ **Tip:** If the mask frame falls backward and is too close to your ears you may need a smaller mask frame.



✱ **Tip:** If the mask frame falls forward on the head and is too close to your eyes you may need a larger mask frame.

Using the Mask

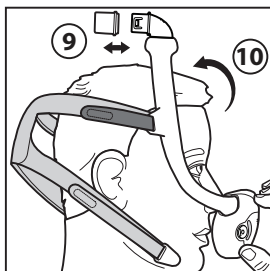
1. Connect the CPAP tubing (included with the CPAP device) to the tubing quick release on the elbow.
2. Turn the therapy device on. Lie down. Breathe normally.
3. Assume different sleeping positions. Move around until comfortable. If there are any excessive air leaks, make final adjustments. Some air leaking is normal.

Tubing Quick Release

The elbow is equipped with a tubing quick release. Pull on the tubing quick release and it will disengage from the elbow and come loose with the tubing. ⑨

Removing the Mask

To keep your adjustments, remove the mask by grasping the cushion and pulling forward away from the nose. Then pull the cushion and mask up and off of the head. ⑩



5 Mask Care

Cleaning Instructions

Daily: Hand wash the non-fabric parts.

Weekly: Hand wash the fabric parts.

1. Disassemble the mask (see **Disassembly** section).
 2. Submerge and hand wash the mask in warm water with liquid dishwashing detergent.
- ⊖ **Note:** Ensure there are no air pockets present inside the mask parts while submerged.
3. Rinse thoroughly.
 4. Lay the headgear and fabric sleeves flat or line dry. Make sure the entire mask is dry before use.
- ⊖ **Note:** Do not place the fabric parts into a clothes dryer.
- ⚠ **Caution:** Any deviation from these instructions may impact the performance of the product.

⚠ Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

Dishwashing Instructions

In addition to hand washing, the mask may be cleaned in the dishwasher once a week.

⚠ Caution: Use a mild liquid dish washing detergent only to wash the mask.

1. Remove the fabric parts. Do not wash the fabric parts in the dishwasher.
2. Wash in the top shelf of the dishwasher.

⊖ Note: Do not use the drying cycle on the dishwasher.

3. Air dry. Make sure the mask is dry before use.

⚠ Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.

6 Assembly and Disassembly

Assembly

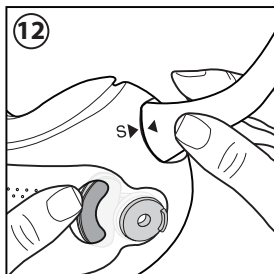
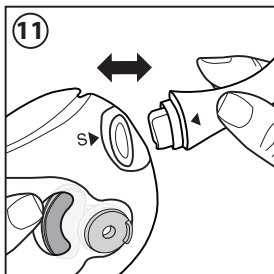
1. Cushion: Press into the mask frame until the cushion clicks into place.

⑪⑫

⊖ Note: The end of the cushion and the opening in the mask frame are 'D' shaped. The cushion end should match the frame.

2. Elbow: Insert into the top of the mask frame.
3. Tubing quick release: Push the tubing quick release onto the elbow until it clicks into place.
4. (Optional) Fabric sleeves: Wrap the sleeves around the mask frame and press the strips together.

⊖ Note: The sleeve seams should be on the outside of the frame.

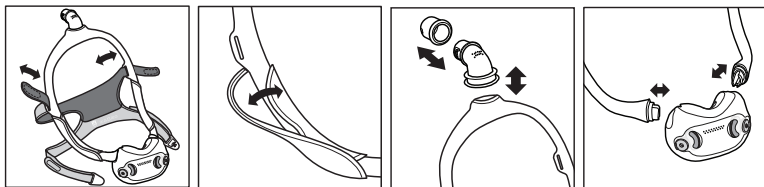


5. Headgear: Slide the headgear top strap tabs into the slots on the mask frame and fold backwards. Attach the magnetic headgear clips.

Note: The Philips Respironics logo will be on the outside and facing up when correctly assembled.

Disassembly

1. Headgear: Undo the headgear tabs and pull through the slots in the mask frame. Turn the magnetic headgear clips away from the mask frame.
2. Fabric sleeves: Undo the strips and remove from the mask frame.
3. Tubing quick release: Pull the tubing quick release from the elbow.
4. Elbow: Pull the elbow from the top of the frame.
5. Cushion: Pull the cushion away from the mask frame.



7 Healthcare Provider & Clinician Information

Useful Life

The useful life of the DreamWear Full Face mask depends on the use conditions and maintenance (cleaning, institutional disinfection, and component replacement) of the device. Inspect the mask parts regularly for damage or wear. Replace components as deemed necessary.

Multi-Patient Use

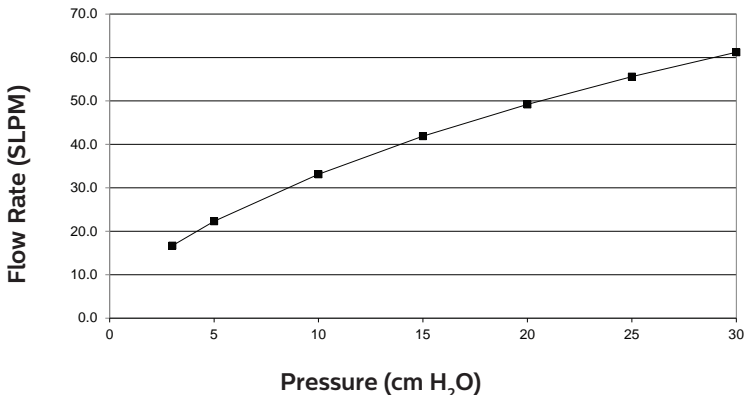
Refer to the Disinfection Guide for Professional Users to reprocess between patients in a clinical setting. Access the latest version of the Disinfection Guide at www.healthcare.philips.com or by contacting customer service at 1-800-345-6443 (USA or Canada only) or +1-724-387-4000.

Specifications

The technical specifications of the mask are provided for your healthcare professional to determine if it is compatible with your CPAP or bi-level therapy device.

⚠ Warning: Use outside of these specifications may result in ineffective therapy. The pressure flow curve shown below is an approximation of expected performance. Exact measurements may vary.

Pressure Flow Curve



Resistance with Flaps Closed to Atmosphere

Drop in Pressure (cm H ₂ O)	at 50 SLPM	at 100 SLPM
All Cushion Sizes	0.9	3.1

Closed to Atmosphere: A minimum of 3 cm H₂O must be maintained to ensure that the flaps close.

Open to Atmosphere: At an airway pressure less than -1 cm H₂O, the flaps will be open.

Inspiratory and Expiratory Resistance with Flaps Open to Atmosphere at 50 SLPM (cm H₂O)

Inspiratory Resistance 0.4

Expiratory Resistance 1.8

Deadspace (mL)

Frame size:	SM	MED	LG
Cushion size:	S: 176.3	S: 179.3	S: 182.2
	M: 182.7	M: 185.7	M: 188.6
	L: 201.3	L: 204.3	L: 207.2
	MW: 185.2	MW: 188.2	MW: 191.1

Sound Levels (dBA)

A-weighted Sound Power Level 24.0

A-weighted Sound Pressure Level at 1 m 16.5

Disposal







Dispose of in accordance with local regulations.








Storage Conditions

Temperature: -4° F to 140° F (-20° C to 60° C)

Relative Humidity: 15% to 95%, non-condensing

8 Symbols Glossary

Symbol	Title and Meaning	Reference
X1	Philips Respironics DreamStation Mask Type and System One Resistance Control Value Indicates the therapy device comfort setting.	-
R_x ONLY	Prescription device Caution: U.S. federal law restricts this device by or on the order of a physician.	-
	Not Made with Natural Rubber Latex Indicates that this mask is not made with natural rubber latex.	-
	Manufacturer Indicates the medical device manufacturer.	IEC 60878 ISO 7000-3082 Symbol 5.1.1, ISO 15223-1
	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.	IEC 60878 ISO 7000-2620 Symbol 5.3.8, ISO 15223-1
	Temperature limit Indicates the storage temperature limits to which the medical device can be safely exposed.	IEC 60878 ISO 7000-0632 Symbol 5.3.7, ISO 15223-1
	Caution, consult accompanying documents.	IEC 60878 Symbol 5.1.2, ISO 15223-1
	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.	IEC 60878 ISO 7000-2492 Symbol 5.1.5, ISO 15223-1

Symbol	Title and Meaning	Reference
	Reorder number Indicates the manufacturer's catalogue number so the medical device can be identified.	ISO 7000-2493 Symbol 5.1.6, ISO 15223-1
	Operator's manual; operating instructions Consult instructions for use.	ISO 7000-1641 Symbol 5.4.3, ISO 15223-1
	Wash by hand Indicates that cleaning the textile article is allowed only by washing by hand.	ISO 7000-3125
	Do not bleach Indicates that bleaching textile article is not allowed.	ISO 7000-3124
	Do not tumble dry Indicates that tumble drying is not allowed in the drying process.	ISO 7000-3109
	Do not iron Indicates that ironing is not allowed.	ISO 7000-3113
	Do not dry clean Indicates that dry cleaning is not allowed.	ISO 7000-3114

ISO 7000:2014, Graphical symbols for use on equipment - Registered symbols

ISO 15223-1:2012, Medical devices - Symbols to be used with medical devices labels - General requirements

IEC/TR 60878: 2015, Graphical symbols for electrical equipment in medical practice

9 Limited Warranty

Respironics, Inc. warrants that its mask systems (including mask frame and cushion) (the “Product”) shall be free from defects of workmanship and materials for a period of ninety (90) days from the date of purchase (the “Warranty Period”). If the Product fails under normal conditions of use during the Warranty Period and the Product is returned to Respironics within the Warranty Period, Respironics will replace the Product. This warranty is nontransferable and only applies to the original owner of the Product. The foregoing replacement remedy will be the sole remedy for breach of the foregoing warranty.

This warranty does not cover damage caused by accident, misuse, abuse, negligence, alteration, failure to use or maintain the Product under conditions of normal use and in accordance with the terms of the product literature, and other defects not related to materials or workmanship.

This warranty does not apply to any Product that may have been repaired or altered by anyone other than Respironics. Respironics disclaims all liability for economic loss, loss of profits, overhead, or indirect, consequential, special or incidental damages which may be claimed to arise from any sale or use of the Product. Some jurisdictions do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN ADDITION, ANY IMPLIED WARRANTY, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS SPECIFICALLY DISCLAIMED. SOME JURISDICTIONS DO NOT ALLOW DISCLAIMERS OF IMPLIED WARRANTIES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS UNDER LAWS APPLICABLE IN YOUR SPECIFIC JURISDICTION.

To exercise your rights under this limited warranty, contact your local authorized Respironics, Inc. dealer or Respironics, Inc. at 1001 Murry Ridge Lane, Murrysville, Pennsylvania 15668, USA, or Respironics Deutschland GmbH & Co KG, Gewerbestraße 17, 82211 Herrsching, Germany.

Limited Warranty for Australia and New Zealand only
Note: For Australian and New Zealand customers this warranty replaces the warranty contained above.

1. Respironics, Inc., a Philips company (“Philips Respironics”), warrants that the Products shall be free from defects of workmanship and materials and will perform in accordance with the Product specifications. 2. This warranty is valid for a period of two (2) years from the date of purchase from an authorized Philips Respironics dealer. 3 If the Product is found to contain a defect of workmanship or materials or fails to perform in accordance with the Product specifications during the applicable warranty period, Philips Respironics will repair or replace, at its option, the defective material or part. 4. The customer is responsible for returning the product to an authorised Philips Respironics dealer, and collecting the product from the authorised Philips Respironics dealer after repair or replacement, at its own cost. Philips Respironics is responsible only for the freight cost of transporting the product between the authorised Philips Respironics dealer and Philips Respironics. Philips Respironics reserves the right to charge an evaluation and postage fee for any returned Product as to which no problem is found following investigation. 5. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to materials or workmanship. 6. The warranty provided by Philips Respironics herein is not transferrable by the Buyer in the event of any sale or transfer of Products purchased by the Buyer from an authorized Philips Respironics dealer. 7. To the extent permitted by law, where the Buyer has the benefit of an implied guarantee under the Australian Consumer Law, but the Product is not of a kind ordinarily acquired for personal, domestic or household use or consumption Philips Respironics’ liability shall be limited, at the option of Philips Respironics, to the replacement or repair of the Product or the supply of an equivalent Product. 8. To exercise your rights under this warranty, contact your local authorised Philips Respironics dealer. A list of all authorised dealers is available at the following link: <http://www.philips.com.au/healthcare>.

Alternatively, you can make a claim under this warranty by contacting Philips Respironics directly at: Philips Electronics Australia Limited, 65 Epping Road, North Ryde NSW 2113, Australia. Tel: 1300 766 488, Email: prcontact@philips.com. 9. The following statement is provided to a Buyer who is a “consumer” under the Australian Consumer Law: *Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the good repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.* 10. The following statement is provided to a Buyer who is a “consumer” under the Consumer Guarantees Act 1993, New Zealand: *Our goods come with guarantees that cannot be excluded under the Consumer Guarantees Act 1993. This guarantee applies in addition to the conditions and guarantees implied by that legislation.*

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