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User Guide

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Pixi™
PEDIATRIC MASK

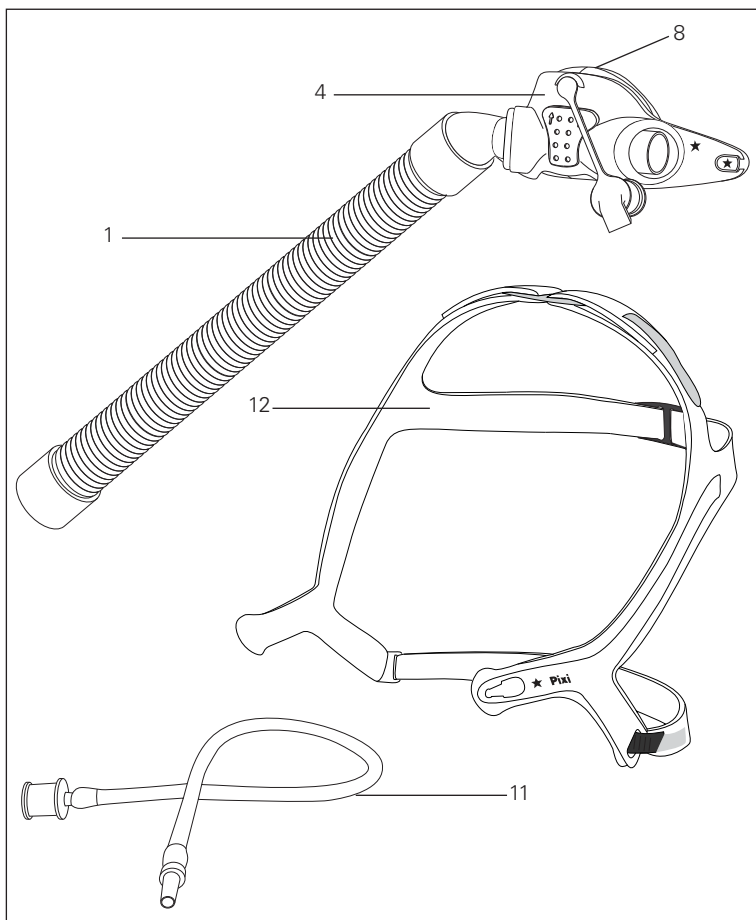
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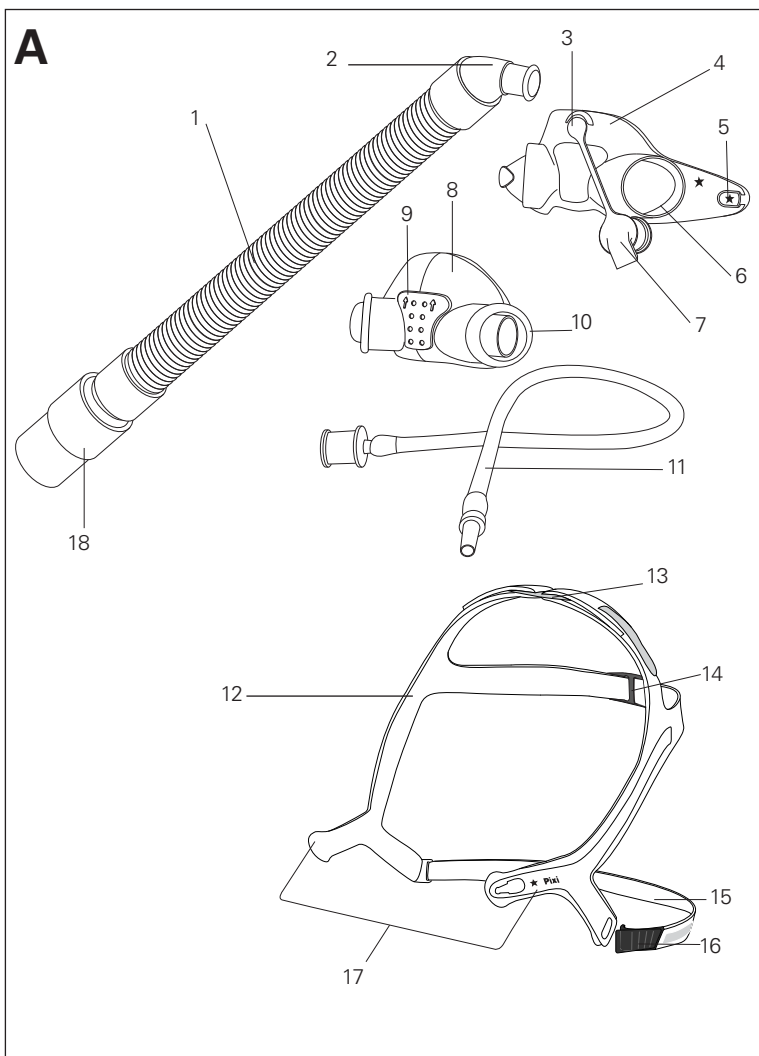
PEDIATRIC MASK

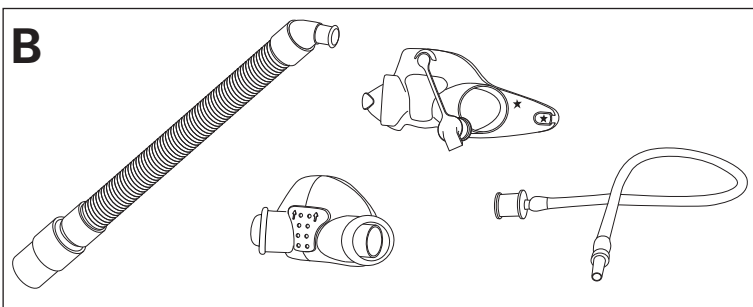
R_X Only

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





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

Item / Composant / Pieza / Item	Description / Description / Descripción / Descrição	Part number / Code produit / Número de pieza / Número da peça
1.	Short tube assembly / Ensemble tuyau court / Conjunto del tubo corto / Conjunto de tubo curto	—
2.	Elbow / Coude / Codo / Cotovelo	—
3.	Plug tether / Point d'attache du bouchon d'obturation / Cabo del tapón / Limitador da tampa	—
4.	Mask frame / Entourage rigide / Armazón de la mascarilla / Armação da máscara	—
5.	Frame nodes / Points de fixation de l'entourage / Nudos del armazón / Ressaltos da armação	—
6.	Mask socket / Logement du masque / Enchufe de la mascarilla / Cavidade da máscara	—
7.	Plug / Bouchon d'obturation / Tapón / Tampa	—
8.	Cushion / Bulle / Almohadilla / Almofada	61033
9.	Vent / Ensemble orifices de ventilation / Orificios de ventilación / Respiradouro	—

Item / Composant / Pieza / Item	Description / Description / Descripción / Descrição	Part number / Code produit / Número de pieza / Número da peça
10.	Cushion shoulder / Rebord de la bulle / Hombro de la almohadilla / Projeção da almofada	—
11.	Pressure port / Port de pression / Puerto de presión / Porta de pressão	—
12.	Headgear / Harnais / Arnés / Arnês	61034
13.	Top headgear strap and buckle (light blue) / Sangle supérieure du harnais et boucle (bleu clair) / Correa superior del arnés y hebilla (celeste) / Correia superior do arnês e fivela (azul claro)	—
14.	Middle headgear strap and buckle (dark blue) / Sangle centrale du harnais et boucle (bleu foncé) / Correa del medio del arnés y hebilla (azul) / Correia central do arnês e fivela (azul escuro)	—
15.	Lower headgear strap / Sangle inférieure du harnais / Correa inferior del arnés / Correia inferior do arnês	—
16.	Quick release clip / Clip de retrait rapide / Broche de abertura inmediata / Presilha de liberação rápida	—
17.	Lower headgear arms / Bras inférieurs du harnais / Brazos inferiores del arnés / Braços inferiores do arnês	—
18.	22 mm Swivel / Pièce pivotante 22 mm / 22 mm Pieza giratoria / 22 mm Peça giratória	—
A	Complete system / Masque complet / Sistema completo / Sistema completo	61030
B	Frame system / Support / Sistema del armazón / Sistema da armação	61035

Thank you for choosing the Pixi Pediatric mask. Please read the entire manual before use.

Intended use

The Pixi Pediatric mask channels airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device ('device').

The Pixi Pediatric mask is:

- to be used by children aged between 2 and 7 for whom continuous positive airway pressure (CPAP) or bilevel therapy has been prescribed
- intended for single-patient re-use in the home and single patient re-use in the hospital/institutional environment.



WARNING

- This mask is designed to provide a stable effective air seal with minimum headgear tension. High headgear tension may lead to facial deformities with long-term use. Regular clinician review of growth patterns and the use of different styles of mask is recommended.
- The mask must be used under qualified supervision for patients who are unable to remove the mask by themselves.
- The mask may not be suitable for those predisposed to aspiration.
- If the mask is prescribed for children with serious congenital conditions or cognitive impairments, then using a device with appropriate alarms is recommended. The correct operation of the complete patient circuit, including alarms must be tested before commencing therapy.
- 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.
- The vent holes must be kept clear and must not sit against the nose.
- 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 vent holes 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 vent holes. However, when the device is not operating, insufficient fresh air will be provided through the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most models of CPAP or bilevel devices.

- This mask should only be used with CPAP or bilevel devices recommended by a physician or respiratory 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.
- Remove and dispose of all packaging before using the mask.

Set up

Determine which side of the cushion the air tubing will be located. Ideally this should be the side that is closest to the device.



Pixi Hint! *If the child has a preference for sleeping on a particular side, this should be considered when determining the location of the device.*

Changing the side of the air tubing

1. To change the side of the air tubing, remove the plug from the cushion.
2. Insert the combined elbow and air tubing until the cushion meets the ridge on the elbow.
3. Ensure the opposite side of the cushion is fully closed by securely inserting the plug into the cushion opening.

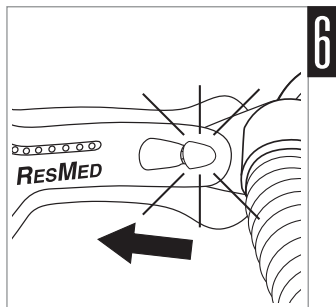
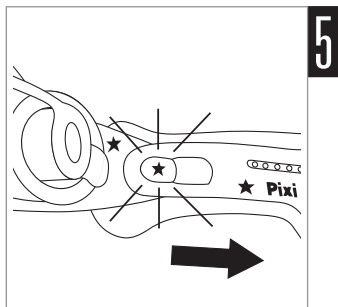
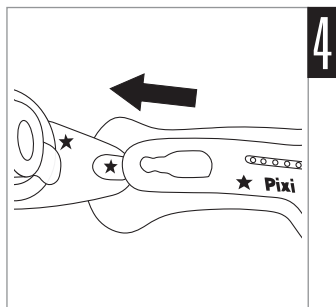
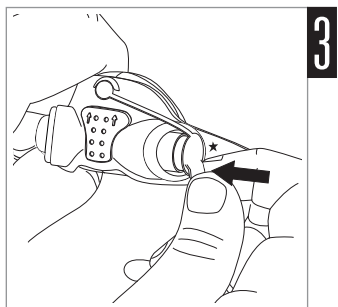
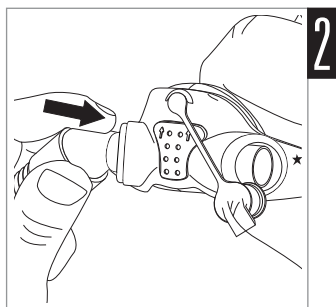
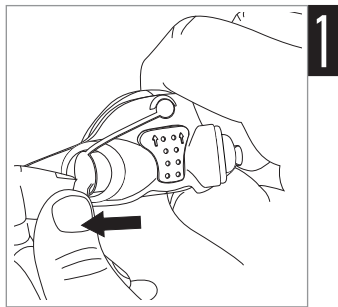
Attaching the headgear

The mask frame has been designed to ensure the headgear is fitted correctly every time.

4. Latch the lower headgear arm with the star onto the frame node with two stars, so that the frame is nested between the plastic and the padding of the headgear.
5. Gently pull the headgear arm into place until it clicks.
6. Repeat steps 4-5 with the other side (without stars).

Set up is now complete and the mask is ready for fitting.

Set up



WARNING

- Ensure that the nasal cushion does not block the nostrils at any time during fitting or use.
- Do not leave long lengths of air tubing around the top of the child's bed. It could twist around the child's head or neck while sleeping.

Fitting

The fitting illustrations show the sequence for obtaining the best fit and comfort when using the mask.

Pixi Hints!

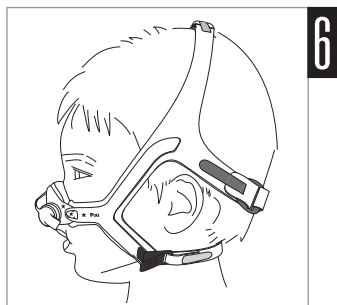
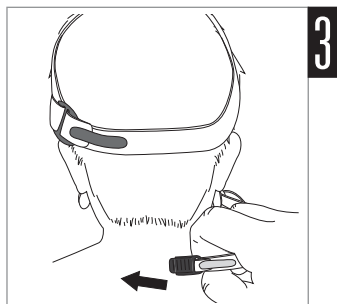
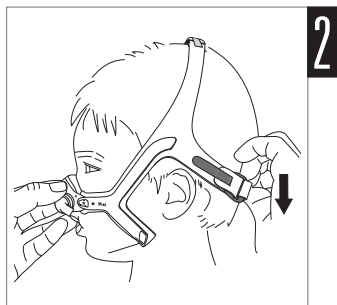
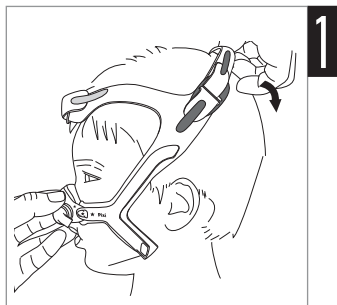


- *If fitting the mask for the first time, we recommend the child be sitting in an upright position to ensure correct fit.*
- *To avoid possible anxiety by the child, ensure all parts of the mask frame and headgear are kept clear from the eyes and eye area.*
- *The child will best adapt to therapy if the mask is correctly fitted before the device is turned on.*

Fitting steps

- 1–2. Hold the mask gently against the child's face, checking that the nose is fully enclosed by the cushion and the mouth is clear – pull the headgear up over the head. Move the middle strap down over the head until it sits across the middle of the back of the head.
3. Keeping your hand on the frame to maintain correct headgear position, bring the lower headgear strap behind the back of the neck.
- 4–5. Attach the lower headgear strap to the mask by holding the tab and hooking the quick release clip onto the lower headgear arm.
6. When fully fitted, the mask and headgear should be positioned as shown. Ensure the top strap is vertically aligned with the top of the ears and the middle strap sits across the back of the head horizontally aligned with the top of the ears.
7. Finally, connect the free end of the short tube assembly to the device air tubing.

Fitting



Adjustment

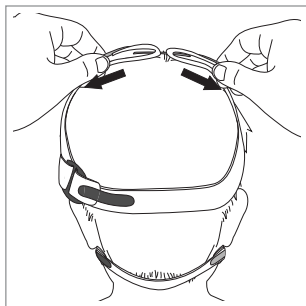
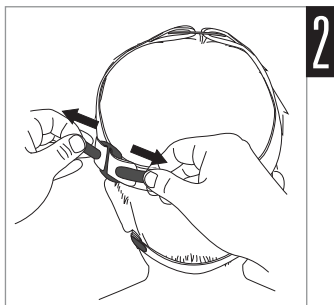
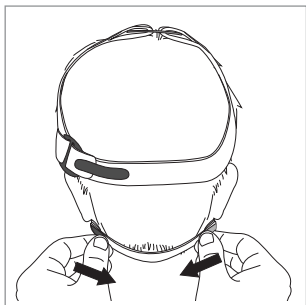
Pixi Hints!



- To achieve optimal seal, adjust the headgear straps starting at the bottom strap and working upwards.
- If the child experiences nasal dryness or irritation, using a humidifier is recommended.

Adjustment steps

1. If necessary, adjust the straps by removing the Velcro® and gently tightening the lower headgear straps until comfortable. Do not overtighten.
- 2-3. Repeat step 1 with both middle and top straps until comfortable.
Note: The mask is designed to fit loosely while still providing an optimal seal. Do not overtighten the straps.



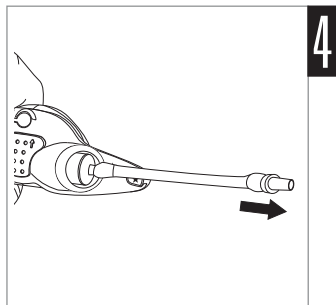
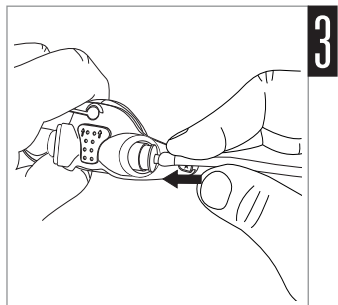
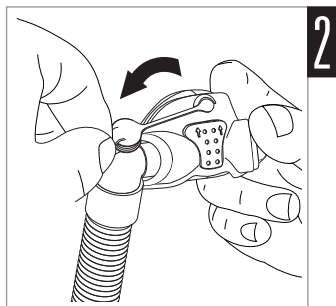
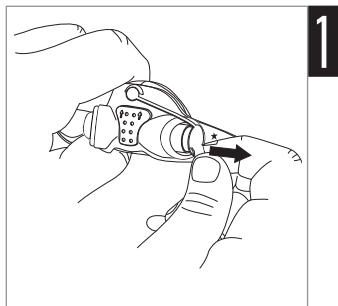
Attaching the pressure port

The pressure port is used to measure the air pressure at your mask so that the correct pressure is set. This happens during the sleep study at the hospital.

The pressure port is also used to deliver oxygen. This can take place in the home or hospital environment. If necessary, your clinician will advise when this is required.

Attachment steps

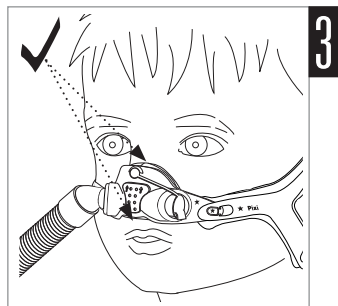
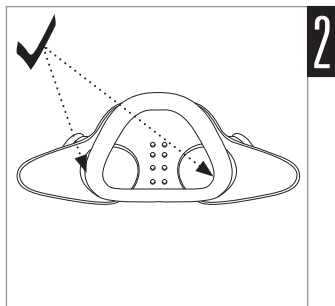
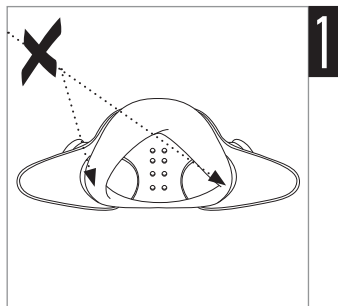
1. Remove the plug from the cushion.
2. Move the plug to the side so that it is not obstructing the vent holes.
3. Insert the larger end of the pressure port into the cushion.
4. Attach the other end of the pressure port to the oxygen system.



Cushion check

Cushion check steps

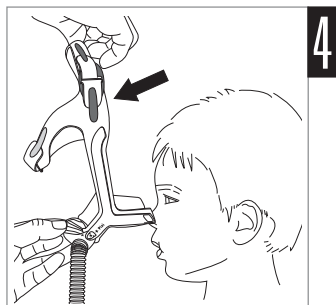
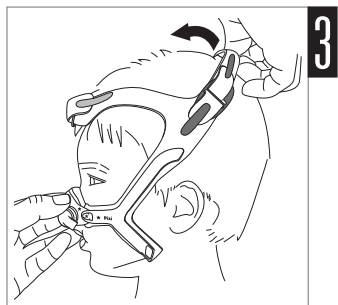
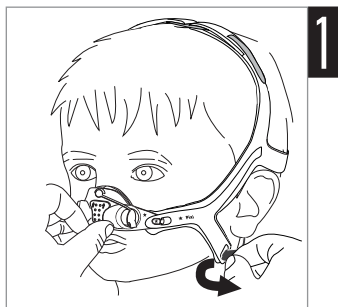
- 1–2. Ensure the cushion is not creased or folded or caught inside the sockets of the mask frame.
3. The Pixi cushion is designed to sit mid-bridge. Ensure that the mask does not block the nose or mouth at any time.



Removal

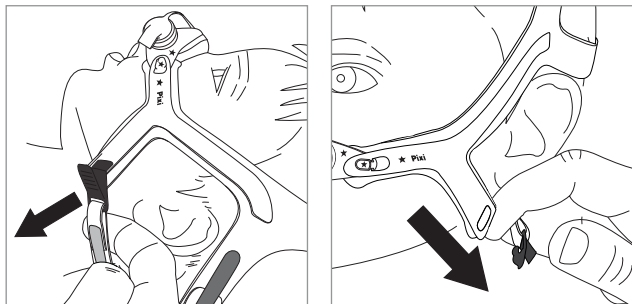
Removal steps

- 1–2. Gently hold the mask against the child's face. Unhook the quick release clip from the lower headgear arm by pulling forward and away from the arm.
- 3–4. Keep holding the mask and remove the headgear by pulling up and over the head towards the face.



Emergency removal

In the event of an emergency, remove the mask by placing your finger under the lower headgear strap and firmly pulling it away from the child—this will activate the quick release clip. Do not use this removal method under normal circumstances.



Disassembly

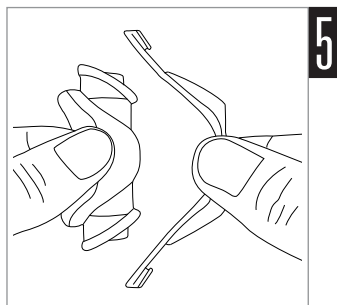
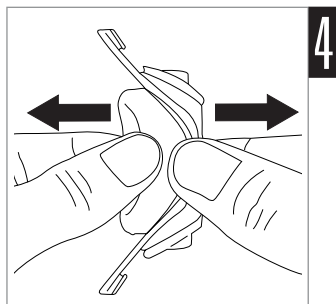
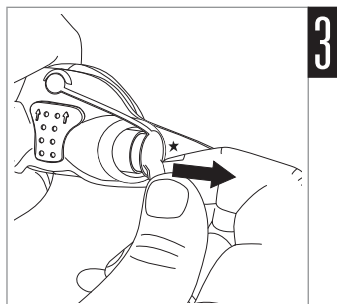
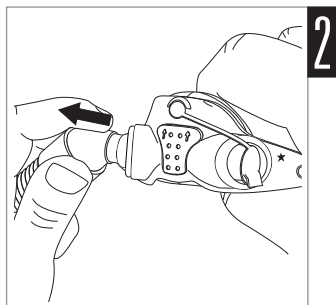
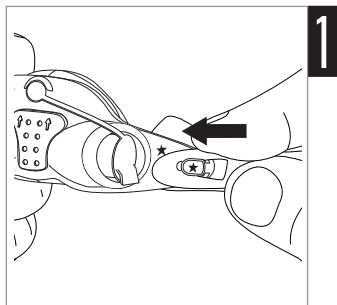
Disassembly steps

1. Detach the headgear from the mask frame by unlatching each of the lower headgear arms from the frame nodes.
2. Remove the combined elbow and air tubing from the mask.
3. Remove the plug from the cushion.
- 4-5. Remove the cushion from the frame by gently pushing it through from the front of the frame and pulling it away from the rear of the mask frame.

WARNING

When disassembling the mask, always keep all accessories and components out of the reach of small children as small parts might present a choking hazard. Seek immediate medical attention if choking occurs or if any small part has been swallowed.

Disassembly



Headgear reassembly



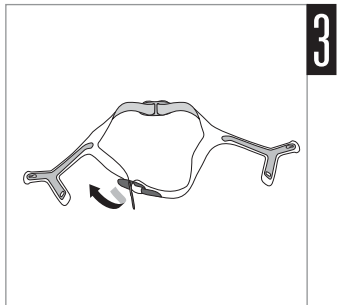
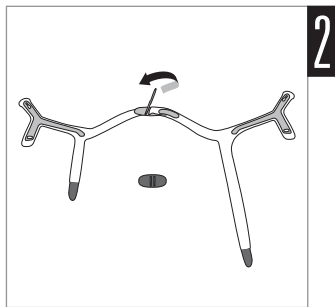
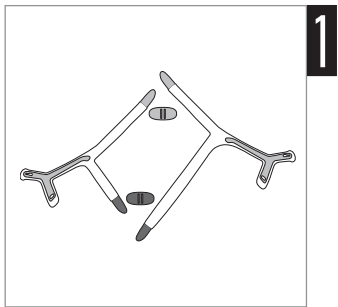
Pixi Hints!

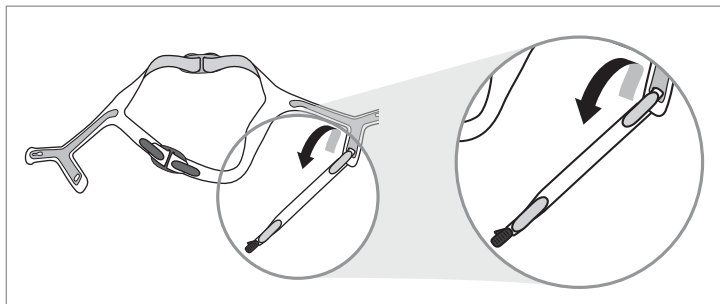
- You don't need to disassemble your Pixi headgear to wash it.
- The Velcro™ straps and plastic buckles have been color coded for ease of assembly.

Headgear reassembly steps

1. Lay the headgear and plastic buckles out on a flat surface as shown, ensuring the lower headgear arms are facing up.
2. Thread each light blue strap up and over the light blue buckle, then secure into place.
3. Thread each dark blue strap up and over the dark blue buckle, then secure into place.
4. Thread the Velcro only end of the lower headgear strap through the lower headgear arm, then secure into place. There is no need to attach the quick release clip to the headgear now.

Ensure that any Velcro or plastic parts are on the outer side of the mask, otherwise your headgear may be incorrectly assembled. The headgear is now ready for fitting. Refer to the Set up illustrations in this guide.

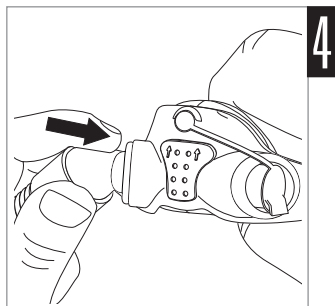
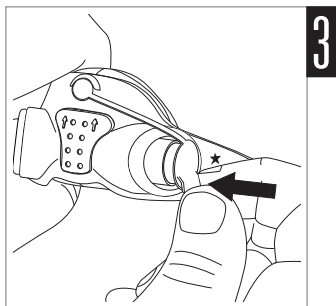
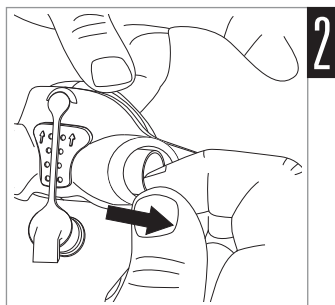
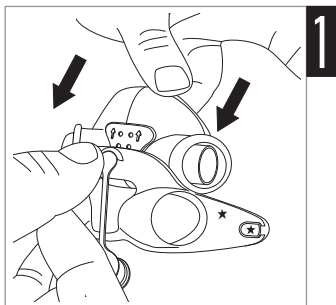




Reassembly

Reassembly steps

1. Insert each side of the cushion into the sockets of the mask frame. Ensure the cushion is oriented correctly. The arrows on the cushion should be pointing up towards the plug tether. The raised vented area of the cushion should also be sitting up against the mask frame.
2. Pull the arms of the cushion through until the collar of the cushion shoulder is sitting against the mask frame.
3. Replace the plug into the appropriate side of the cushion.
4. Insert the combined elbow and air tubing into the other side of the cushion, ensuring that it is fully inserted.
5. Reattach the headgear. Refer to the Attaching the headgear illustrations in this user guide.



Cleaning the mask

The mask and headgear should only be gently handwashed.

Daily/After each use:

- Disassemble the mask components according to the disassembly instructions.
- Thoroughly clean the separated mask components (excluding headgear), by gently rubbing in warm (approximately 86°F/30°C) water using mild soap.
- To optimize the mask seal, facial oils should be removed from the cushion after use.
- Use a soft bristle brush to clean the vent.
- Inspect each component and, if required, repeat washing until visually clean.
- Rinse all components well with drinking quality water and allow to air dry out of direct sunlight.
- When all components are dry, reassemble according to the reassembly instructions.

Weekly:

- Handwash the headgear. It can be washed without being disassembled.



WARNING

Do not use aromatic-based solutions or scented oils (eg, eucalyptus or essential oils), bleach, alcohol or products that smell strongly (eg, citrus) to clean any of the mask components. Residual vapours from these solutions can be inhaled if not rinsed thoroughly. They may also damage the mask.



CAUTION

If any visible deterioration of a system component is apparent (cracking, crazing, broken parts, tears etc), or, if after cleaning, any component remains unclean, the component should be discarded and replaced.

Troubleshooting

Problem / possible cause

Solution

Mask is too noisy

Vent is blocked or partially blocked.

If the vent requires cleaning, use a soft bristle brush.

Elbow or plug is incorrectly inserted.

Remove the elbow and plug from the mask and then reassemble according to the instructions.

Mask leaks around the face

Mask is not positioned correctly.

Gently pull the cushion away from the face to reinflate. Reposition the mask according to the instructions.

Air leaking around the nose

Mask is not tightened correctly.

Tighten the bottom and middle headgear straps. The top strap is designed to sit quite loosely. Do not overtighten.

Turn off the device and remove the mask. Refit the mask according to the instructions. Ensure you position the cushion correctly on the face before pulling headgear over the head.

The mask does not fit properly

Mask may be incorrectly assembled.

Disassemble the mask and reassemble according to the instructions.

Cushion may be dirty.

Clean the cushion according to the instructions.

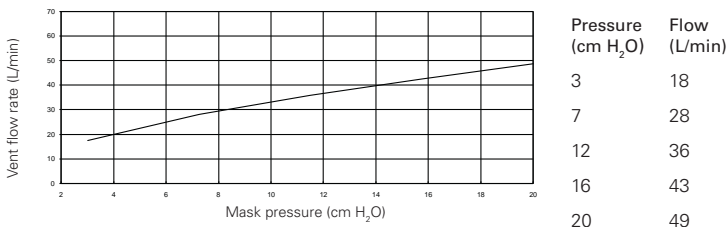
 **WARNING**

- 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 device function.
- Discontinue using this mask if the child has any adverse reaction to the use of the mask, and consult your physician or sleep therapist.
- 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 type of CPAP or bilevel devices.
- As with all masks, some rebreathing may occur at low CPAP pressures.
- Refer to your device manual for details on settings and operational information.

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.



Dead space information

Physical dead space is the empty volume of the mask to the end of the swivel. It is 101.7 mL.

Therapy pressure 3 to 20 cm H₂O

Compliance

Mask compliance between 5 cm H₂O and 15 cm H₂O is less than 1.57 mL/cm H₂O

Resistance

Drop in pressure measured (nominal)
at 50 L/min: 0.8 cm H₂O
at 100 L/min: 3.1 cm H₂O

Environmental conditions

Operating temperature: +41°F to +104°F
(+5°C to +40°C)
Operating humidity: 15% to 95% non-condensing.
Storage and transport: -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.
1.38" (H) x 16.93" (W) x 1.57" (D)
35 mm (H) x 430 mm (W) x 40 mm (D)

Notes:

- The mask system does not contain PVC, DEHP or phthalates.
- This product does not contain 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

 Caution, consult accompanying documents;  Batch Code;  Catalogue number;  Temperature limitation;  Humidity limitation;  Does not contain natural rubber latex;  Manufacturer;  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;  Keep away from rain;  This way up;  Fragile, handle with care.;  European Authorized Representative;  Prescription only (In the US, Federal law restricts these devices to sale by or on the order of a physician).

Limited warranty

ResMed Ltd (hereafter 'ResMed') warrants that your ResMed mask system (including mask frame, cushion, headgear and tubing) shall be free from defects in material and workmanship from the date of purchase for the period of 90 days or in the case of disposable masks the maximum use period. 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 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.



Manufacturer:

ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia.

Distributed by:

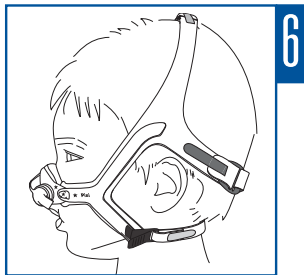
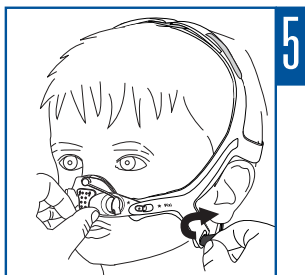
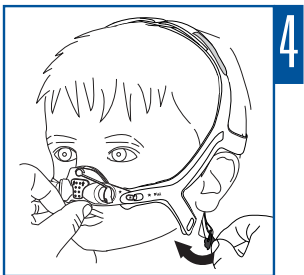
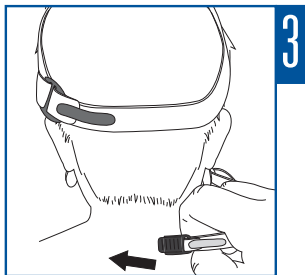
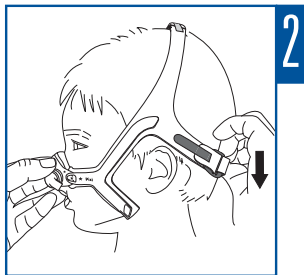
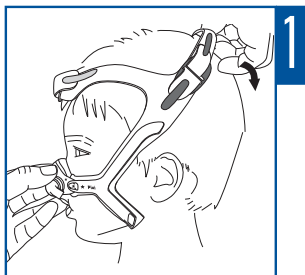
ResMed Corp 9001 Spectrum Center Boulevard San Diego CA 92123 USA.



ResMed (UK) Ltd 96 Milton Park Abingdon Oxfordshire OX14 4RY UK.

See www.resmed.com for other ResMed locations worldwide.

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