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 MultiDoctorShop
Medical products at home

We provide the official
document of the manufacturer
www.multidoctorshop.com

User Guide

English



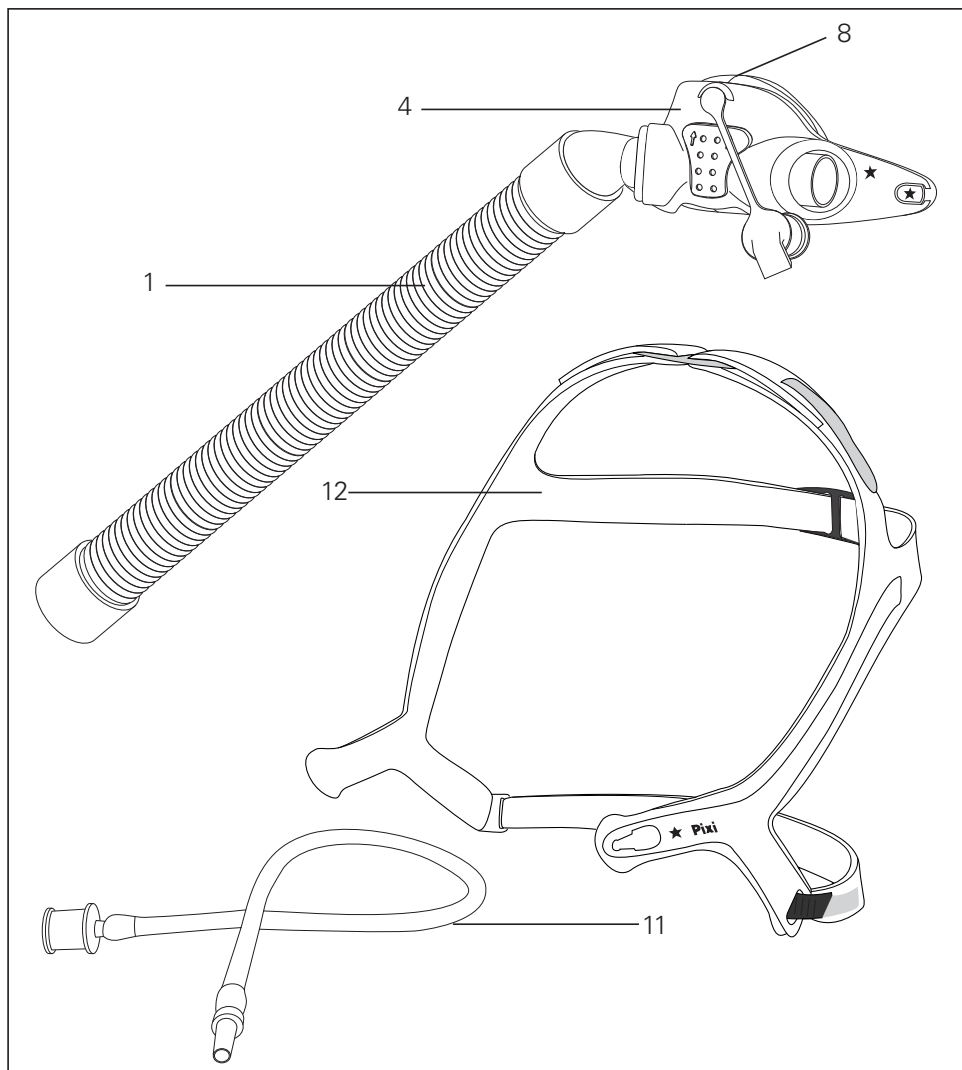
Pixi™
PEDIATRIC MASK

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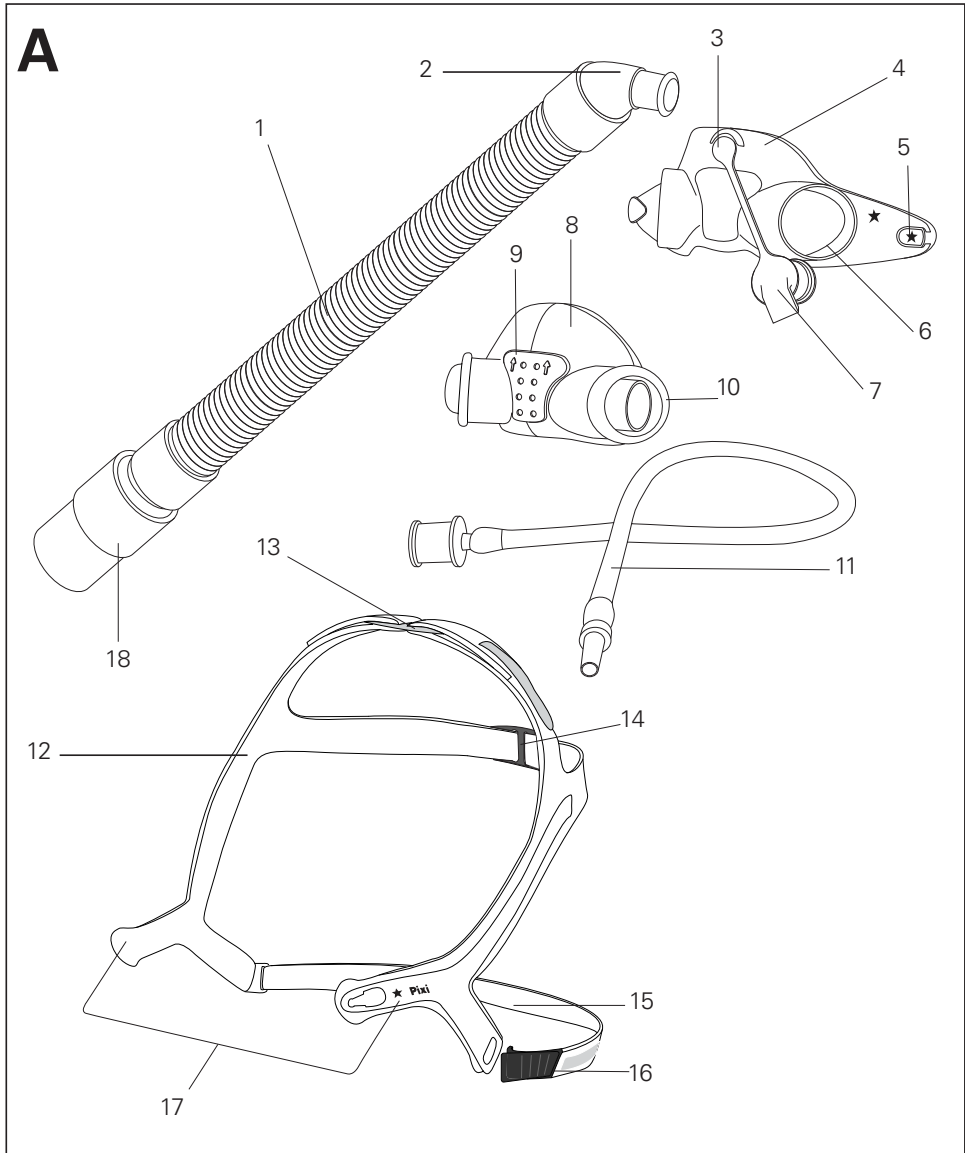
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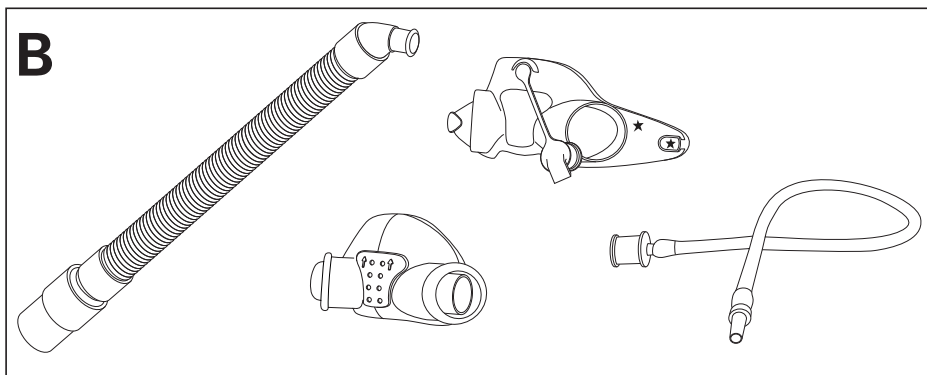
PEDIATRIC MASK

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Tartalomjegyzék / Содержимое / İçindekiler / Obsah / Obsah**



**Mask components / Maskenkomponenten /
Composants du masque / Componenti della maschera /
Piezas de la mascarilla / Componentes da máscara /
Maskeronderdelen / Εξαρτήματα της μάσκας /
Elementy maski / A maszk részei / Компоненты маски / Maske
bileşenleri / Součásti masky / Komponenty masky**





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Item / Artikel / Composant / Elemento / Artículo / Item / Item / Στοιχείο / Część / Tétel / Часть / Madde / Položka / Položka	Description / Beschreibung / Description / Descrizione / Descripción / Descrição / Omschrijving / Περιγραφή / Opis / Leírás / Описание / Açıklama / Popis / Popis	Part number / Teilenummer / Code produit / Codice prodotto / Número de pieza / Referência / Onderdeelnnummer / Αριθμός καταλόγου / Numer części / Cikkszám / Номер детали / Parça numarası / Číslo součásti / Číslo části
1.	Short tube assembly / Verbindungsschlauch- Satz / Ensemble tuyau court / Gruppo circuito corto / Conjunto de tubo corto / Conjunto de tubo curto / Korte slang-assemblage / Συγκρότημα σωλήνα μικρού μήκους / Zespół krótkiej rury / Rövid csőszerelevény / Короткая трубка в сборе / Kısa tüp tertibatı / Krátká trubice / Zostava krátkej trubice	—
2.	Elbow / Kniestück / Coude / Gomito girevole / Codo / Cotovelo / Bocht / Γωνία / Kolanko / Könyök / Отвод / Dirsek / Rameno / Koleno	—

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3.	Plug tether / Verschlussbefestigung / Point d'attache du bouchon d'obturation / Attacco del tappo / Amarre del tapón / Amarra do tampão / Bevestigingspunt afsluitdop / Πρόσδεση πώματος / Мосование затyczki / Dugóögztó / Страховочный тросик крышки / Kapak yuları / Uprínka zátky / Uzdička zátky	—
4.	Mask frame / Maskenrahmen / Entourage rigide / Telaio della maschera / Armazón de la mascarilla / Armação da máscara / Maskerframe / Πλαίσιο μάσκας / Ramka maski / A maszk kerete / Корпус маски / Maske çerçevesi / Têlo masky / Rám masky	—
5.	Frame nodes / Rahmenanschlüsse / Points de fixation de l'entourage / Nodi del telaio / Enganches del armazón / Encaixes da armação / Frameknopjes / Κόμβοι πλαισίου / Występy ramki / Rögzítőbűtykök a kereten / Выступы корпуса / Çerçeve düğümleri / Příkladné body těla masky / Spinacie kolíky rámu	—
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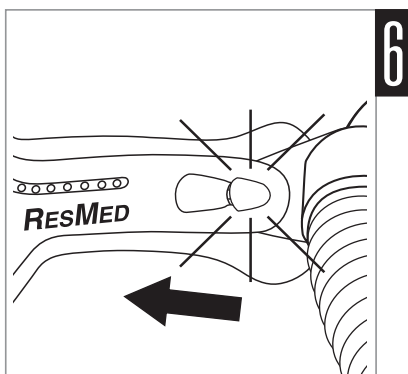
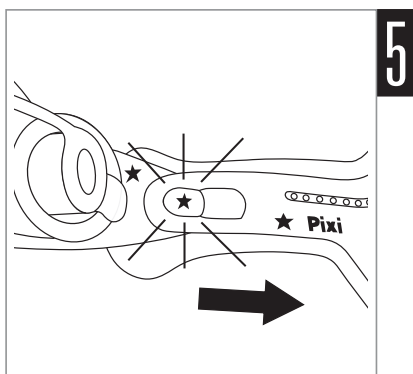
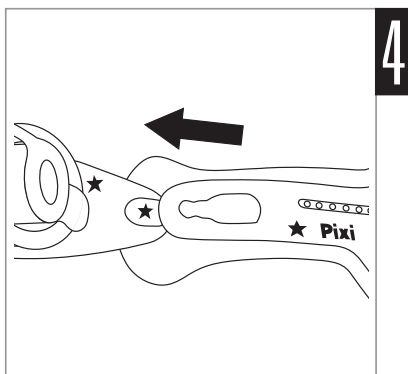
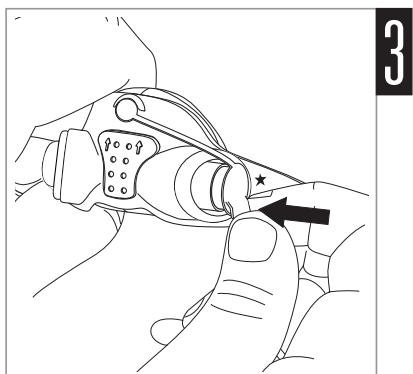
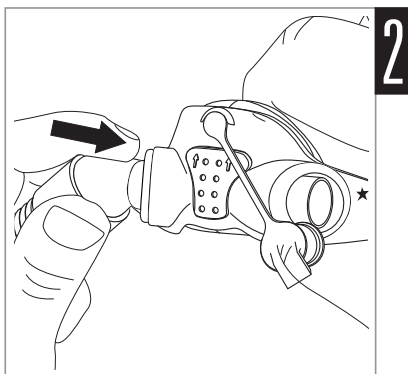
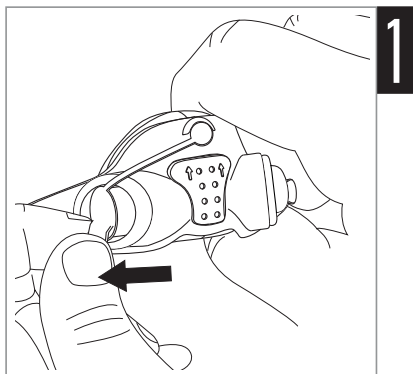
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9.	Vent / Ausatemöffnung / Ensemble orifices de ventilation / Fori per l'esalazione / Orificios de ventilación / Respiradouro / Ventilatiegedeelte / Άνοιγμα εξαερισμού / Otwór odprowadzający powietrze / Szellőzőnyílások / Вентиляционные отверстия / Hava deliği / Odvzdušňovací otvor / Ventil	—
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11.	Pressure port / Druckanschluss / Port de pression / Presa della pressione / Puerto de presión / Porta de pressão / Drukpoort / Θύρα πίεσης / Port ciśnienia / Nyomásport / Порт давления / Basınç portu / Tlakový port / Tlakový port	—
12.	Headgear / Kopfband / Harnais / Copricapo / Arnés / Arnês / Hoofdbandenstel / Ιμάντες κεφαλής / Część nagłowna / Fejránt / Головной фиксатор / Başlık / Náhlavní souprava / Náhlavná súprava	61034

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13.	<p>Top headgear strap and buckle (light blue) / Oberes Kopfband und Clip (hellblau) / Sangle et boucle supérieures du harnais (bleu clair) / Cinghia e fi bbia superiore del copricapo (azzurro) / Correa superior del arnés y hebilla (azul claro) / Correia e fivela superiores do arnés (azul-claro) / Bovenste hoofdband en hoofdbandgesp (lichtblauw) / Πάνω λουράκι ιμάντων κεφαλής και αγκράφα (γαλάζιο) / Górný pasek części nagłownej ze sprzączką (jasnoniebieski) / Felső fejpántszíj és szorítókarocs (világoskék) / Верхний ремешок головного фиксатора и пряжка (голубого цвета) / Üst başlık bandı ve tokası (açık mavi) / Horní páska a přezka náhlavní soupravy (světlemodrá) / Horný popruh a spona náhlavnej súpravy (svetlomodré)</p>	—
14.	<p>Middle headgear strap and buckle (dark blue) / Mittleres Kopfband und Clip (dunkelblau) / Sangle et boucle du milieu du harnais (bleu foncé) / Cinghia e fi bbia intermedia del copricapo (blu) / Correa central del arnés y hebilla (azul oscuro) / Correia e fivela intermédias do arnés (azul-escuro) / Middelste hoofdband en hoofdbandgesp (donkerblauw) / Μεσαίο λουράκι ιμάντων κεφαλής και αγκράφα (σκούρο μπλε) / Środkowy pasek części nagłownej ze sprzączką (ciemnoniebieski) / Középső fejpántszíj és szorítókarocs (sötétkék) / Средний ремешок головного фиксатора и пряжка (темно-синего цвета) / Orta başlık bandı ve tokası (koyu mavi) / Střední páska a přezka náhlavní soupravy (tmavomodrá) / Stredný popruh a spona náhlavnej súpravy (tmavomodré)</p>	—

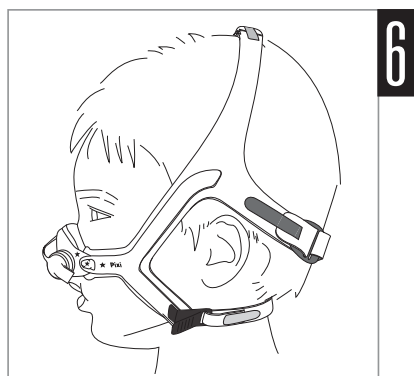
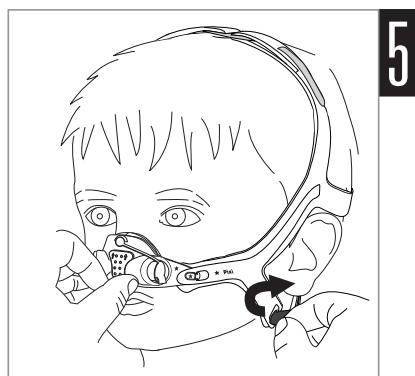
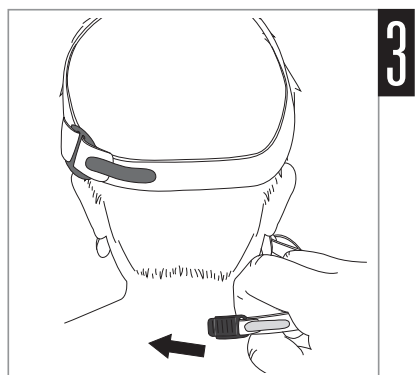
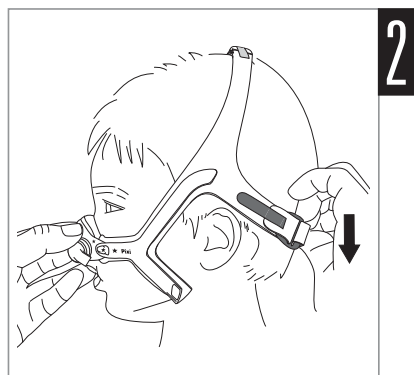
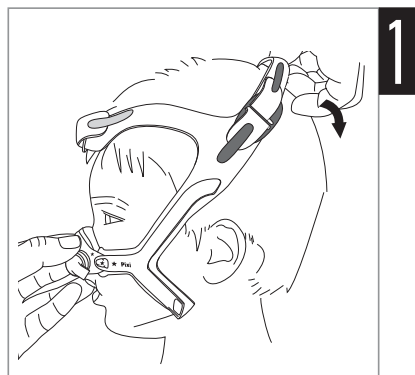
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15.	Lower headgear strap / Unteres Kopfband / Sangle inférieure du harnais / Cinghia inferiore del copricapo / Correa inferior del arnés / Correia inferior do arnês / Onderste hoofdband / Κάτω λουράκι μάντων κεφαλής / Dolny pasek części nagłownej / Alsó fejpántszíj / Нижний ремешок головного фиксатора / Alt başlık bandı / Spodní pásek náhlavní soupravy / Dolný náhlavný popruh	—
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17.	Lower headgear arms / Untere Kopfbandhalter / Bras inférieurs du harnais / Bracci inferiori del copricapo / Brazos inferiores del arnés / Braços inferiores do arnês / Wangstukken / Κάτω βραχίονες μάντων κεφαλής / Dolne odgałęzienia części nagłownej / Alsó fejpántmervítők / Нижние планки головного фиксатора / Alt başlık kolları / Spodní raménka náhlavní soupravy / Dolné ramená náhlavnej súpravy	—
18.	22 mm Swivel / 22 mm Drehadapter / Pièce pivotante 22 mm / Giunto rotante da 22 mm / Pieza giratoria de 22 mm / Peça giratória de 22 mm / Draaibare kop 22 mm / Στροφέας 22 mm / Końcówka obrotowa 22 mm / 22 mm-es csukló / Шарнирное соединение, 22 мм / 22 mm Halka / 22mm kloubové upevnění / 22 mm kĺb	—

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A	Complete system / Komplettes System / Masque complet / Sistema completo / Sistema completo / Sistema completo / Volledig systeem / Πλήρες σύστημα / Cely system / Teljes rendszer / Полная система / Komple sistem / Kompletní systém / Kompletný systém	61031
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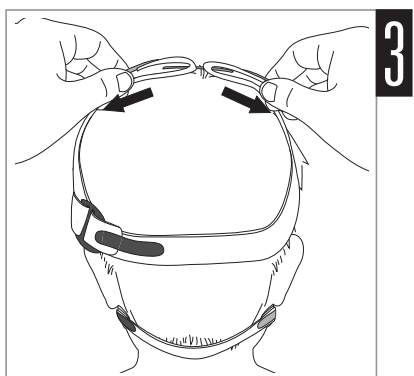
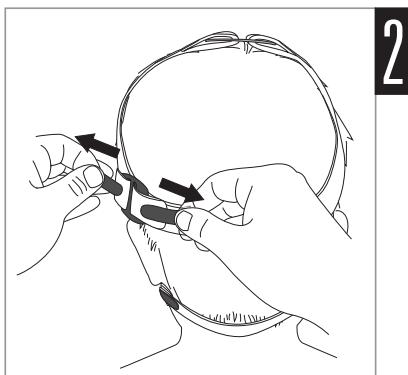
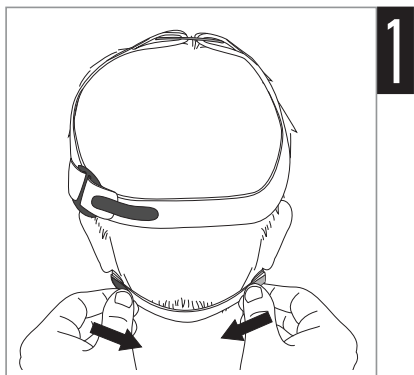
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Przygotowanie / Összeszerelés / Установка / Kurulum / Nastavení
masky / Zostavenie**



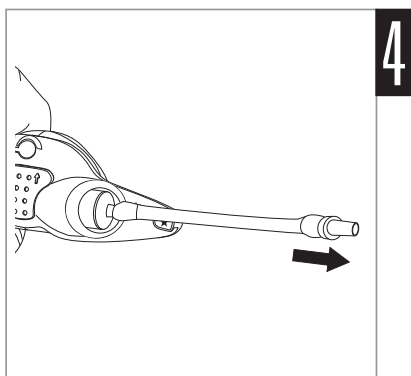
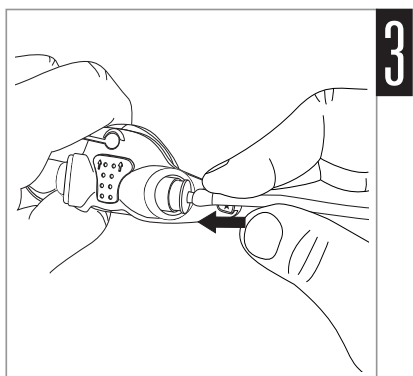
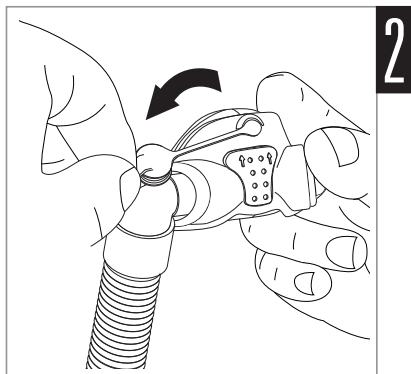
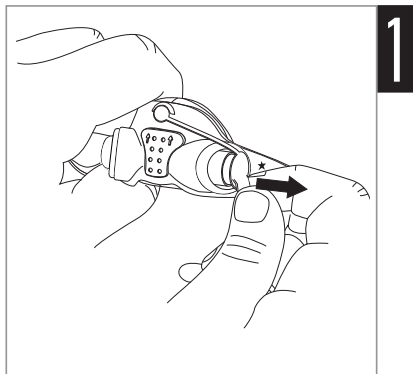
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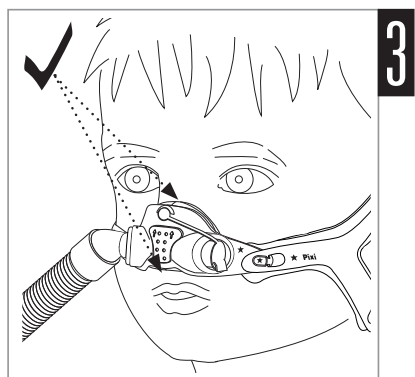
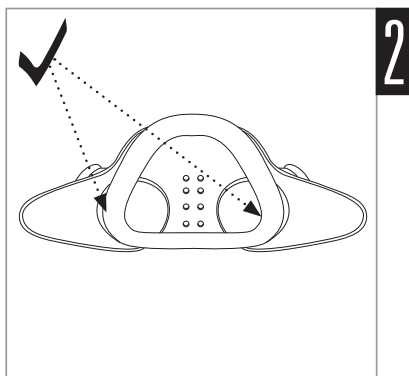
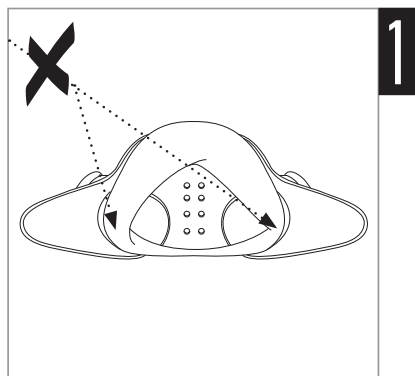
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Регулировка / Ayarlama / Úprava velikosti masky / Prispôsobenie**



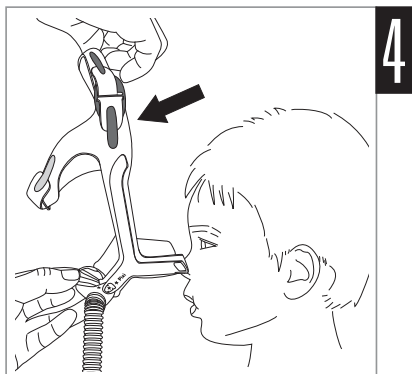
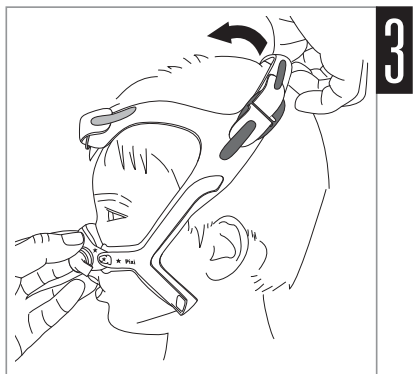
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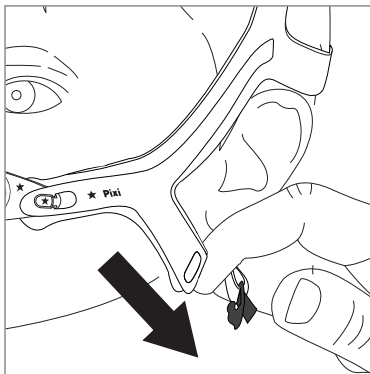
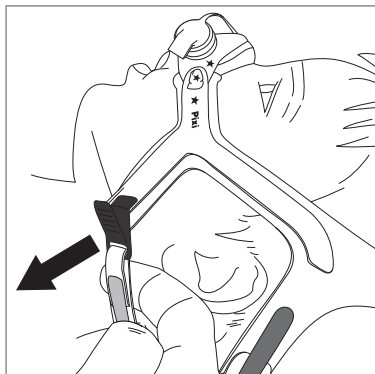
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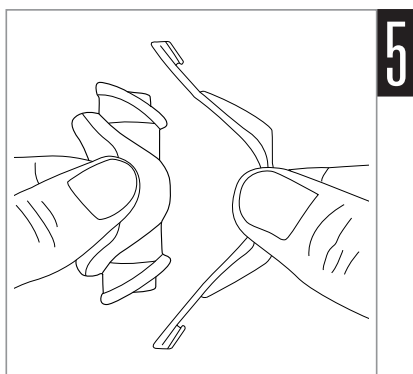
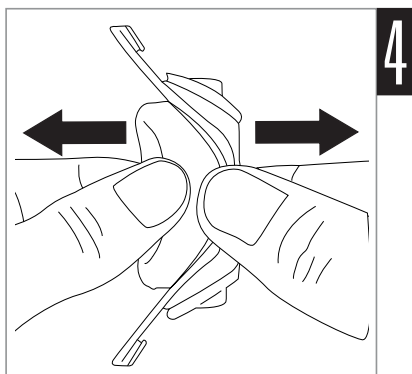
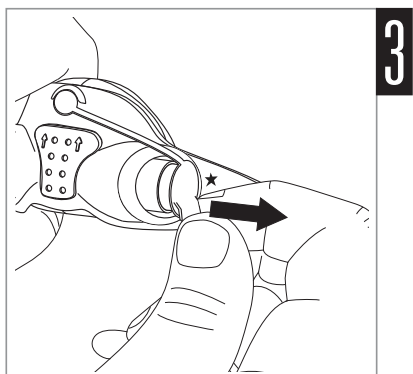
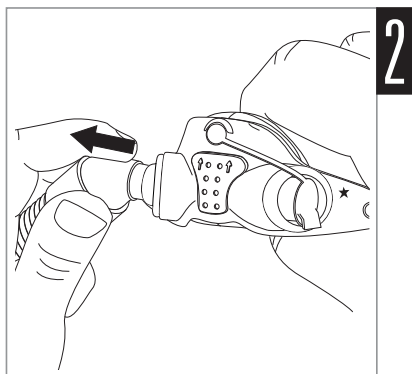
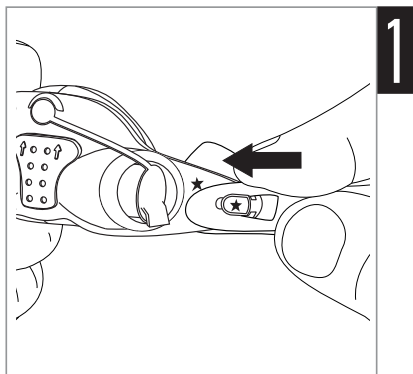
**Removal / Abnehmen / Retrait / Rimozione / Para quitarla /
Remoção / Afnemen / Αφαίρεση / Zdejmovanie / Eltávolítás /
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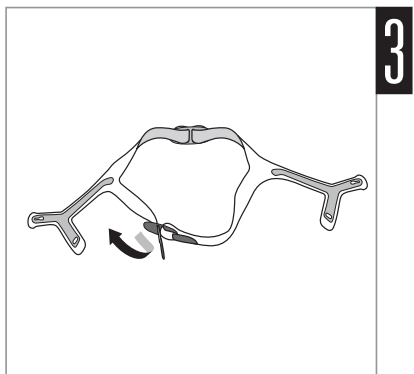
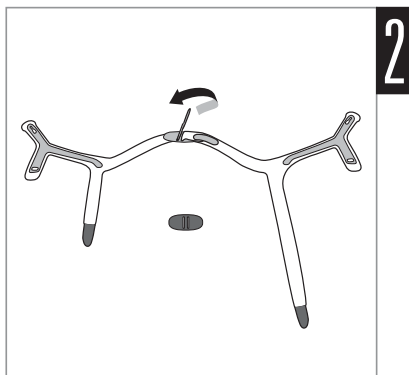
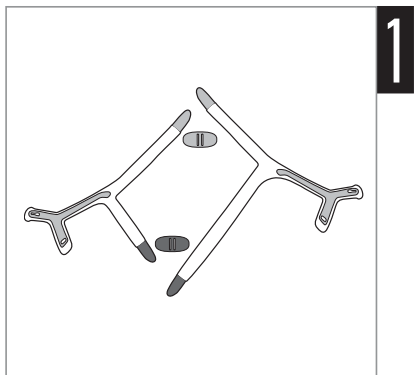
Emergency removal / Abnehmen im Notfall / Retrait d'urgence / Rimozione d'emergenza / Para quitarla en caso de emergencia / Remoção de emergência / Afnemen bij noodsituatie / Αφαίρεση έκτακτης ανάγκης / Zdejmovanie w sytuacji awaryjnej / Eltávolítás vészhelyzet esetén / Экстренное снятие / Acil durumda çikarma / Nouzové sejmutí / Urgentné snímanie

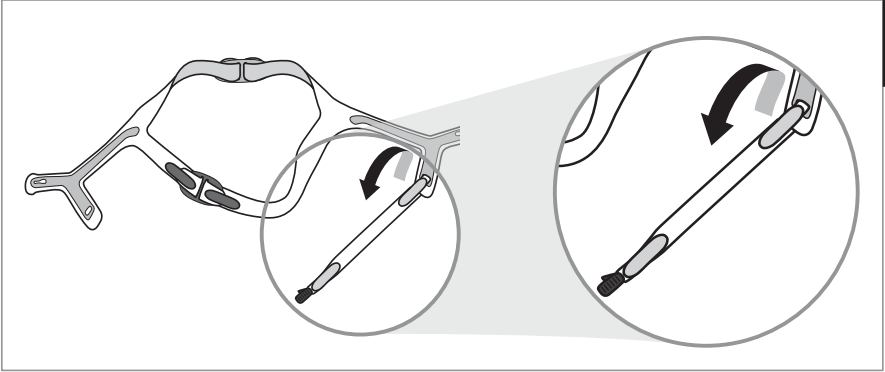


**Disassembly / Auseinanderbau / Démontage /
Smontaggio / Desmontaje / Desmontagem / Demonteren /
Αποσυναρμολόγηση / Demontaž / Szétszerelés / Разборка /
Sökme / Demontáž masky / Rozobratie**

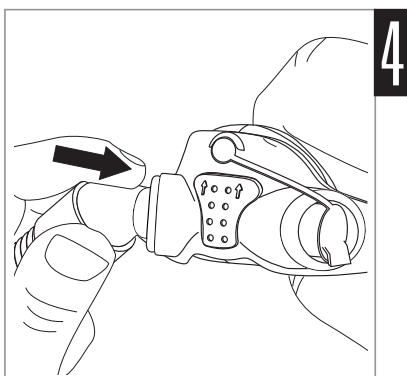
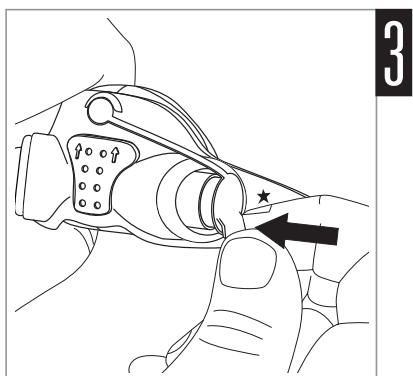
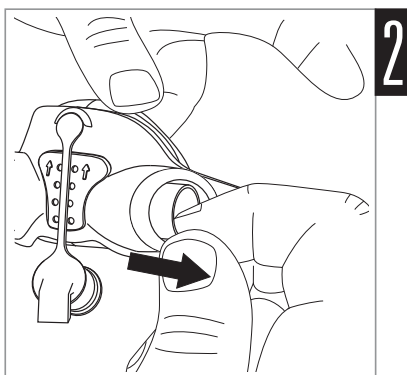
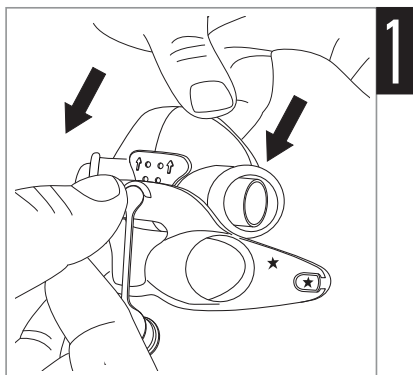


Headgear reassembly / Wiederausammenbau des Kopfbandes / Remontage du harnais / Riassetraggaggio del copricapo / Montaje del arnés / Nova montagem do arnes / Opnieuw monteren van het hoofdbandenstel / Βήματα επανασυναρμολόγησης μάντων κεφαλής / Ponowny montaż części nagłownej / A fejpántszij ismételt összeszerelése / Сборка головного фиксатора / Başlıđın yeniden montajı / Opětovné sestavení masky / Opätovné zostavenie náhlavnej súpravy





**Reassembly / Wiedezusammenbau / Remontage / Riassemblaggio /
Montaje / Nova montagem / Opnieuw monteren / Επανασυναρμολόγηση /
Ponowny montaż / Ismételt összeszerelés / Сборка / Yeniden montaj /
Opětovné sestavení masky / Opätovné zostavenie**



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.

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.

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.

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 30°C) water using mild soap.
- To optimise 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

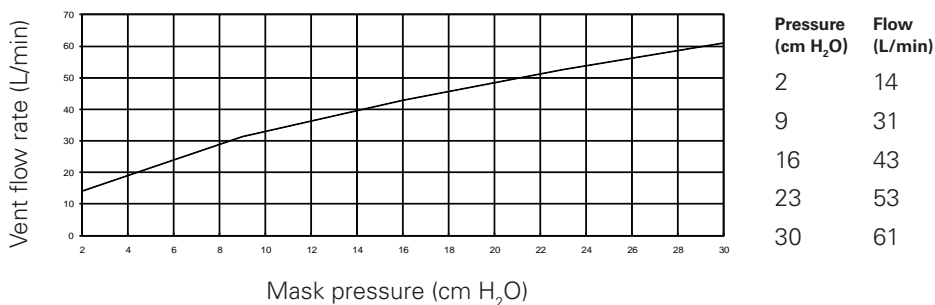
- The technical specifications of the mask are provided for your clinician to check that they are compatible with the CPAP or bilevel device. If used outside specification or if used with incompatible devices, the seal and comfort of the mask may not be effective, optimum therapy may not be achieved, 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.

Technical specifications

Therapy pressure	2 to 30 cm H ₂ O
Compliance	Mask compliance between 5 cm H ₂ O and 15 cm H ₂ O is less than 1.57 mL/cm H ₂ O
Resistance	Drop in pressure measured (nominal) at 50 L/min: 0.8 cm H ₂ O at 100 L/min: 3.1 cm H ₂ O
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 40.6 dBA, with uncertainty 4 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 32.6 dBA, with uncertainty 4 dBA.
Environmental conditions	Operating temperature: +5°C to +40°C Operating humidity: 15% to 95% non-condensing. Storage and transport: -20°C to +60°C Storage and transport humidity: up to 95% non-condensing.
Gross dimensions	Mask fully assembled with elbow assembly – no headgear. 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;  European Authorised Representative;  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.

Consumer warranty

ResMed acknowledges all consumer rights granted under the EU Directive 1999/44/EG and the respective national laws within the EU for products sold within the European Union.



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.



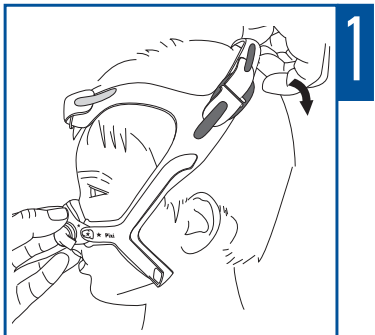
For patent information, see www.resmed.com/ip.

Pixi is a trademark of ResMed Ltd.

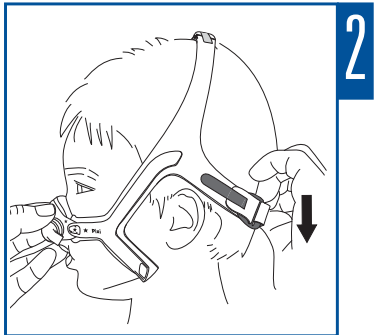
Velcro is a trademark of Velcro Industries B.V.

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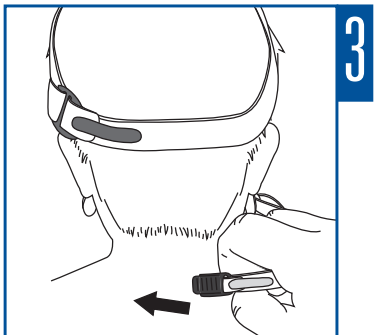




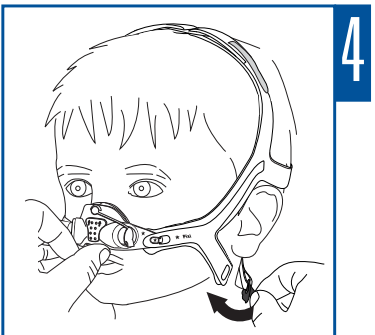
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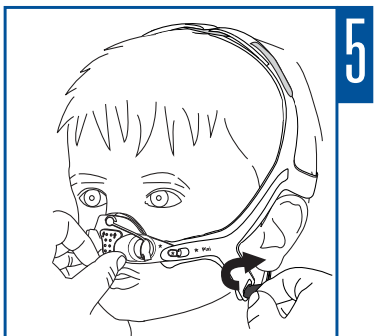
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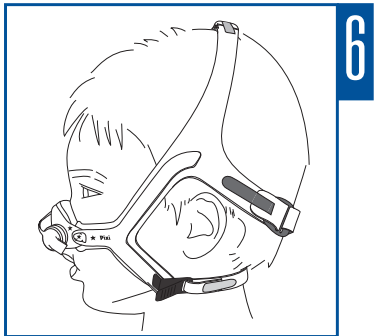
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