

## TECHNICAL DATA SHEET

<b>Device picture</b>	
<b>Reference number and device name</b>	472711 Respireo SOFT Child
<b>GMDN code:</b>	57815
<b>Medical device classification:</b>	CLASS IIa
<b>CE marking:</b>	Certificate n°679/MDD in accordance with the requirements of the European Directive 93/42/EEC and following modifications – Annex II
<b>Manufacturer:</b>	Air Liquide Medical Systems S.r.l. Via dei Prati, 62 25073 Bovezzo (BS) - ITALY
<b>Manufacturer certifications:</b>	UNI CEI EN ISO 13485:2016 UNI EN ISO 14001:2015 BS OHSAS 18001:2007
<b>Product normative references:</b>	ISO 17510:2015

<b>Description:</b>	<p>The components of the mask are:</p> <ul style="list-style-type: none"> <li>● a main body in soft material;</li> <li>● a tube assembly constituted by a elbow fitting with calibrated vent ports, a flexible tube, a port for oxygen/pressure with a cap and a swivel fitting (22mm male) to connect the patient circuit;</li> <li>● a headgear to hold the mask on the baby face equipped by two plastic hooks to facilitate the connection of the headgear to the main body.</li> </ul>
<b>Intended use:</b>	Respireo Soft Child is a non-invasive nasal mask used for treating respiratory failure in children between the ages of 1,5 and 6 years.

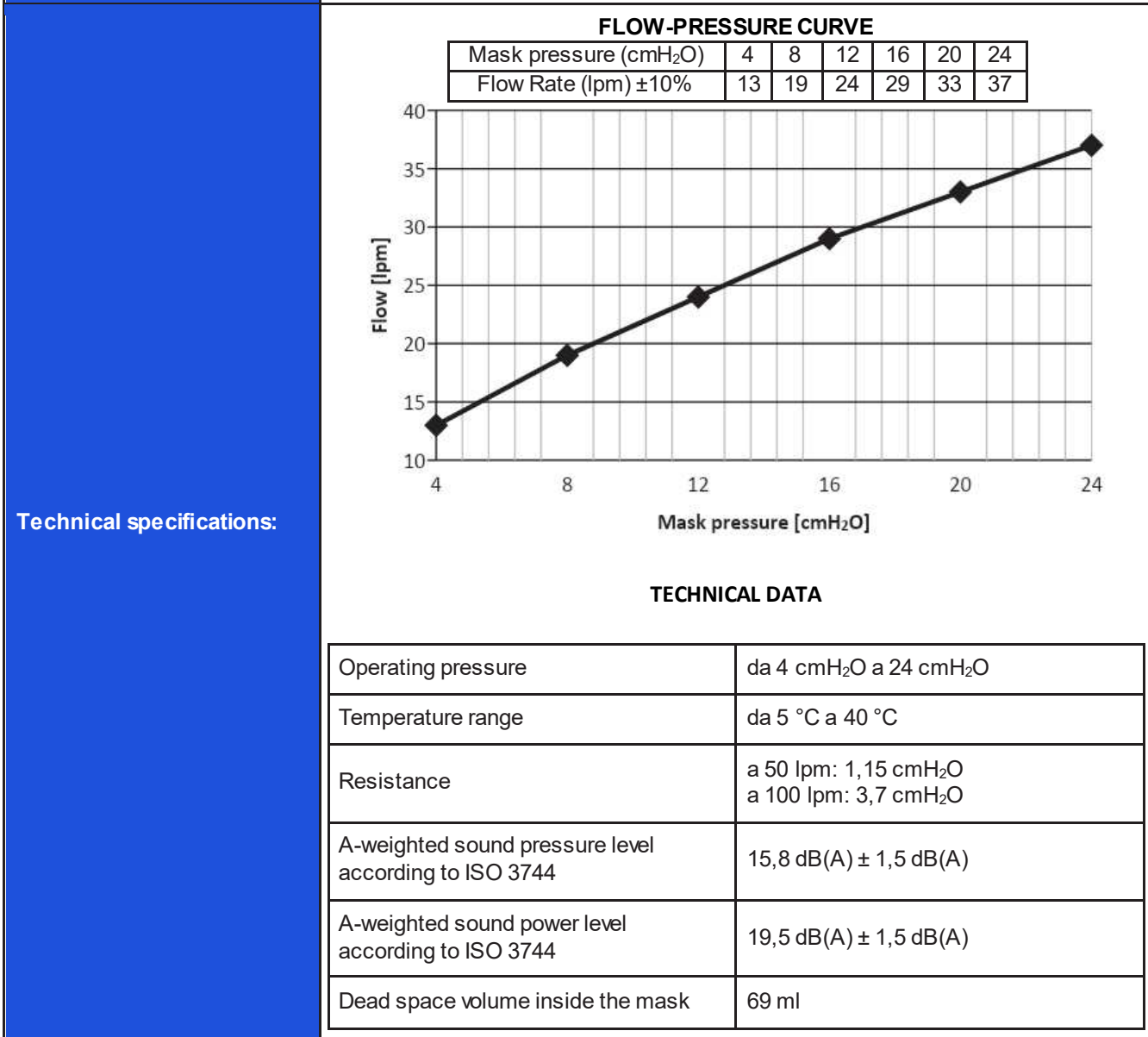
Respireo Soft Child is designed for use by children in continuous positive airway pressure (CPAP) or Bi-level positive airway pressure treatment.  
Respireo Soft Child is designed for use by a single patient at home or more than one in the hospital environment.

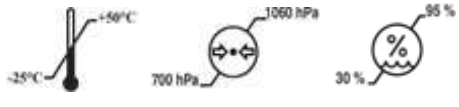
**Materials:**

- Main body: Silicone + Polycarbonate
- Tube assembly: Polycarbonate + Ethylene + Acetalic + Silicone
- Headgear: Nylon/Polyurethane/UBL

Where applicable, these materials comply with the characteristics of Biocompatibility according to UNI EN ISO 10993-1.

LATEX FREE  
DEHP FREE



	Gross dimensions	89 mm x 122 mm x 359 mm
	Weight	70 g
Cleaning, disinfection and sterilization:	<p><b>SINGLE-PATIENT MASK CLEANING</b> First, disassemble all the components. <b>After each use:</b> Carefully clean the cushion and the mask frame in warm water (about 30°C) using mild soap. Thoroughly rinse under the tap and leave in the air to dry, out of direct sunlight. <b>Every 7 days repeat the same procedure for cleaning the headgear as well.</b></p> <p><b>DISINFECTION</b> The mask must be disassembled for disinfection. Immerse the components in a cold solution of disinfectant (e.g. a solution containing up to 2% sodium hypochlorite), following the manufacturer's instructions. ⚠ Check if the disinfectant solution is compatible with the all materials used for the production of the medical device.</p> <p><b>REPROCESSING THE MASK FOR RE-USE WITH OTHER PATIENTS</b> The mask can be regenerated up to 12 times, using one of the following methods:</p> <ul style="list-style-type: none"> <li>• high-level thermal disinfection;</li> <li>• high-level chemical disinfection;</li> <li>• sterilisation in an autoclave at 121°C for no more than 20 minutes;</li> <li>• Sterrad gas-plasma sterilisation.</li> </ul> <p>Full details are contained in "Guide for multi-patient use of masks": check online at <a href="http://www.device.airliquidehealthcare.com/it">www.device.airliquidehealthcare.com/it</a> or contact your dealer.</p> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>- Do not clean the mask with solutions containing alcohol, aromatic compounds, humidifiers, antibacterial agents, hydrating agents or aromatic oils as they would damage the product and reduce its life.</li> <li>- Do not leave the mask immersed for more than 10 minutes.</li> <li>- Do not clean the mask in the dishwasher.</li> <li>- Check carefully all the components to make sure there are no soap deposits or foreign bodies inside the mask.</li> <li>- The headgear must not be disinfected or used by another patient</li> <li>- In case of thermal disinfection and autoclave sterilization, the tube assembly must be replaced.</li> </ul>	
	User guide:	User guide in each package
Storage conditions:		
Traceability:	Lot number	
Packaging:	Individual package: plastic bag 170 mm x 105 mm x 75 mm Multiple package (containing 5 pieces): carton box 595 mm x 220 mm x 130 mm	
Warranty:	120 days	
Introduction on the market:	2016	
Spare parts:	472714 - Kit Headgear SOFT Child	

	472709 - Kit 10 SOFT Baby/Child vented tube assembly
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Date of revision:	07/2019 Rev.D
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*Technical Department*