Clinical Use Only

RESMED

ResMed Masks

Disinfection and Sterilization Guide

NASAL MASKS

Mirage Activa™
NASAL MASK

Mirage Kidsta™
NASAL MASK

Mirage Vista™
NASAL MASK

Ultra Mirage™ II
NASAL MASK

Ultra Mirage™
NON-VENTED NASAL MASK

NASAL PILLOWS SYSTEMS

Mirage Swift™ II *NEW*
NASAL PILLOWS SYSTEM

Mirage Swift™
NASAL PILLOWS SYSTEM

FULL FACE MASKS

Mirage™
NON-VENTED FULL FACE MASK SERIES 2

Mirage Liberty™ *NEW*
FULL FACE MASK

Mirage Quattro™ *NEW*
FULL FACE MASK

Ultra Mirage™
FULL FACE MASK

Ultra Mirage™ *NEW*
NON-VENTED FULL FACE MASK

ResMed Masks – Disinfection and Sterilization Guide

This Disinfection and Sterilization Guide is intended for multipatient use of the mask or nasal pillows[1] system in a sleep lab, clinic or hospital. If you use the mask as a single user in the home, refer to the User Guide for cleaning instructions.

This Disinfection and Sterilization Guide is organized into two sections:

1. ResMed Masks

Table 1 in this section lists the masks to which this guide applies; for specific details about a mask, refer to the User Guide. For each mask, the table specifies:

- The disinfection or sterilization procedures for which the mask is validated.
- The parts that cannot be treated. Mask parts that cannot be treated should be replaced with new parts between patients. Check the Components Card/Guide on the website www.resmed.com for a list of available replacement parts for each mask system.
- The number of disinfection or sterilization cycles for which the mask is validated. If a healthcare facility requires an additional disinfection or sterilization process after reassembly, the number of validated cycles is halved.

Note: *The headgear does not require disinfection or sterilization. Thoroughly washing the headgear between patients is acceptable.*

Cleaning the Headgear

WARNING

Do not iron the headgear as the material is heat sensitive and will be damaged.

Handwash the headgear in warm 86°F (30°C) water using mild soap or diluted dishwashing detergent. Rinse well and allow it to air dry out of direct sunlight.

2. ResMed Validated Procedures

In this section, Tables 2.1 to 2.3 describe ResMed's recommended and validated procedures, for cleaning, disinfection and sterilization of the mask. The procedures are presented in accordance with the standard *ISO 17664: Sterilization of Medical Devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices.*

The procedural steps for disinfection and/or sterilization of the medical devices vary regionally. We advise that each healthcare facility consults its own procedure before carrying out the following instructions.

WARNINGS and CAUTIONS

- ResMed cannot give any assurance that deviations from the procedures listed in this guide, and their effect on the performance of the product, will be acceptable.
- Mask components should not be subjected to autoclave or ethylene-oxide gas sterilization.
- When using detergents, disinfectants or sterilization agents, always follow the manufacturer's instructions.

1 References to masks in this guide refer to ResMed masks *and* nasal pillows systems.

1. ResMed Masks

Note: *Not all masks are available in all regions.*

Table 1: ResMed Masks

Mask	ResMed Validated Disinfection or Sterilization Procedures			Parts that cannot be treated[1]	Number of cycles
	Option 1 High-Level Thermal Disinfection (see Table 2.1)	Option 2 High-Level Chemical Disinfection (see Table 2.2)	Option 3 STERRAD Sterilization (see Table 2.3)		
Mirage Activa Nasal Mask	Yes	Yes	Yes[3]	Swivel, inlet tube	15
Mirage Kidsta Nasal Mask	Yes	Yes	Yes[3]	Swivel, inlet tube	15
Mirage Vista Nasal Mask	Yes	Yes	Yes[3]	Swivel, inlet tube	15
Ultra Mirage II Nasal Mask	Yes	Yes	No	None[4]	15
Ultra Mirage Non-vented Nasal Mask	Yes	Yes	Yes[3]	None	15
Mirage Swift II ***NEW*** Nasal Pillows System	Yes	Yes	Yes[3]	Short tube assembly	15
Mirage Swift Nasal Pillows System	Yes	Yes	Yes[3]	Short tube assembly	15
Mirage Non-vented Full Face Mask Series 2	Yes	Yes	Yes[3]	None	15
Mirage Liberty ***NEW*** Full Face Mask	Yes	Yes[2]	Yes	Swivel, Inlet tube	20
Mirage Quattro ***NEW*** Full Face Mask	Yes	Yes[2]	Yes	None	20
Ultra Mirage Full Face Mask	Yes	Yes	Yes[3]	Valve membrane	15
Ultra Mirage ***NEW*** Non-Vented Full Face Mask	Yes	Yes	Yes	None	15

1 Parts that cannot be disinfected or sterilized should be replaced when using between patients.
2 Not validated for Cidex Plus.
3 Not validated for STERRAD NX.
4 The Ultra Mirage Mask is not validated for STERRAD Sterilization.

2. ResMed Validated Procedures

Note: *The Sterility Assurance Level (SAL) of the reusable mask components is 10^{-6} or 1 in a million, when the mask components are disinfected or sterilized according to the following procedures.*

Table 2.1: Option 1 (High-Level Thermal Disinfection)

	Option 1 (High-Level Thermal Disinfection)
Disassembly	Disassemble the mask according to the instructions in the User Guide.
Cleaning	1. Clean the individual parts of the mask with a soft bristle brush for one minute while soaking them in detergent or disinfectant[1]. Pay particular attention to all crevices and cavities. 2. Rinse the components twice by agitating them vigorously in drinking quality water (5 litres per mask).
Drying	Allow the mask components to air dry out of direct sunlight.
Pre-disinfection	Not validated.
Drying	Not validated.
Disinfection (high-level thermal disinfection)	1. Using a certified hot water disinfection system, soak the disinfectable mask components using one of the temperature-time combinations[2] listed in the following sections. Based on prEN ISO 15883-1, the mask has been tested at the following temperature-time combinations: 158°F (70°C) for 100 minutes 167°F (75°C) for 30 minutes 176°F (80°C) for 10 minutes 194°F (90°C) for 1 minute. 2. On completion, remove the mask components from the hot water disinfection system.
Drying	Drying is achieved as part of the disinfection process.
Inspection	Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discoloration of the silicone components may occur and is acceptable.
Packaging & Storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -4°F to 140°F (-20°C to 60°C).

1 **Cleaning:** ResMed has tested the disinfectant Alconox™ (diluted at 1%).

2 **Disinfection:** ResMed masks have been validated, for the given number of cycles, using the above temperature-time combinations. The device used for testing was Branson™ LTH 1828-24 hot water bath.
These time and temperature combinations have been calculated and predicted from known thermal inactivation kinetics of vegetative micro-organisms subjected to thermal disinfection (prEN/ISO 15883-1) and they are inclusive of the time-temperature combination recommended by the APIC (Associations for professionals in Infection Control and Epidomology).

Table 2.2: Option 2 (High-Level Chemical Disinfection)

	Option 2 (High-Level Chemical Disinfection)
Disassembly	Disassemble the mask according to the instructions in the User Guide.
Cleaning	1. Clean the individual parts of the mask with a soft bristle brush for one minute while soaking them in detergent or disinfectant[1]. Pay particular attention to all crevices and cavities. 2. Rinse the components twice by agitating them vigorously in drinking quality water (5 litres per mask).
Drying	Allow the mask components to air dry out of direct sunlight.
Pre-disinfection	Not validated.
Drying	Not validated.
Disinfection (high-level chemical disinfection)	1. Soak the disinfectable mask components in a commercially available solution of ortho-phthalaldehyde 0.55% (eg, CIDEX™ OPA) or glutaraldehyde 3.4% (eg, CIDEX Plus™)[2]. 2. Rinse the mask components in drinking quality water (5 litres per mask).
Drying	Allow the mask components to air dry out of direct sunlight.
Inspection	Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discoloration of the silicone components may occur and is acceptable.
Packaging & Storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -4°F to 140°F (-20°C to 60°C).

1 **Cleaning:** ResMed has tested the disinfectant Alconox (diluted at 1%).
2 **Disinfection:** ResMed masks have been validated, for the given number of cycles, using solutions of ortho-phthalaldehyde (0.55% CIDEX OPA for 20 minutes) or glutaraldehyde (3.4% CIDEX Plus for 20 minutes).

Table 2.3: Option 3 STERRAD Sterilization

	Option 3 (STERRAD Sterilization)
Disassembly	Disassemble the mask according to the instructions in the User Guide.
Cleaning	1. Clean the individual parts of the mask with a soft bristle brush for one minute while soaking them in detergent or disinfectant[1]. Pay particular attention to all crevices and cavities. 2. Rinse the components twice by agitating them vigorously in drinking quality water (5 litres per mask).
Drying	Allow the mask components to air dry out of direct sunlight.
Pre-disinfection	Not validated.
Drying	Not validated.
Disinfection	Not validated.
Drying	Not validated.
Packaging prior to Sterilization[2]	Package the mask components as described in the manufacturer's instructions for the STERRAD (100S or NX) Sterilization System. ***Note:*** The use of pouches is not recommended.
Sterilization	Follow the manufacturer's instructions for the STERRAD (100S or NX) Sterilization System[3].
Drying	Drying is achieved as part of the sterilization process.
Inspection	Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discoloration of the silicone components may occur and is acceptable.
Packaging & Storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -4°F to 140°F (-20°C to 60°C).

1 **Cleaning:** ResMed has tested the disinfectant Alconox (diluted at 1%).
2 **Packaging prior to Sterilization:** ResMed masks have been validated using the tray method for packaging prior to sterilization.
3 **Sterilization:** ResMed masks have been validated, for the given number of cycles, using the STERRAD 100S or NX Sterilization System.

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