INSTRUCTION MANUAL

Heated CPAP Tubing Compatible with
ResMed AirSense™ 10 machines

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PART NUMBER: **CTUB06S10**
OEM: **37298**

HEATED CPAP TUBING COMPATIBLE WITH RESMED AIRSENSE™ 10 MACHINES

This heated-wire breathing tube is developed to be compatible with the ResMed AirSense™ 10 machines. Our unique design helps prevent condensate from forming within the CPAP heated air stream during CPAP therapy.

This condition of condensation is commonly known as “rainout” and is usually the result of temperature and humidity differentials between the device versus the surrounding air. When attached to the ResMed AirSense™ 10 machines, the heated CPAP tubing device helps prevent this rainout by controlling the airflow temperature, creating an environment to maintain water in its vapor form. The heated CPAP tube when used in line on the ResMed AirSense™ 10 machines helps keep moisture droplets in the air stream and not on your nose, face and mouth, making your experience more comfortable.

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2. Electrical connector
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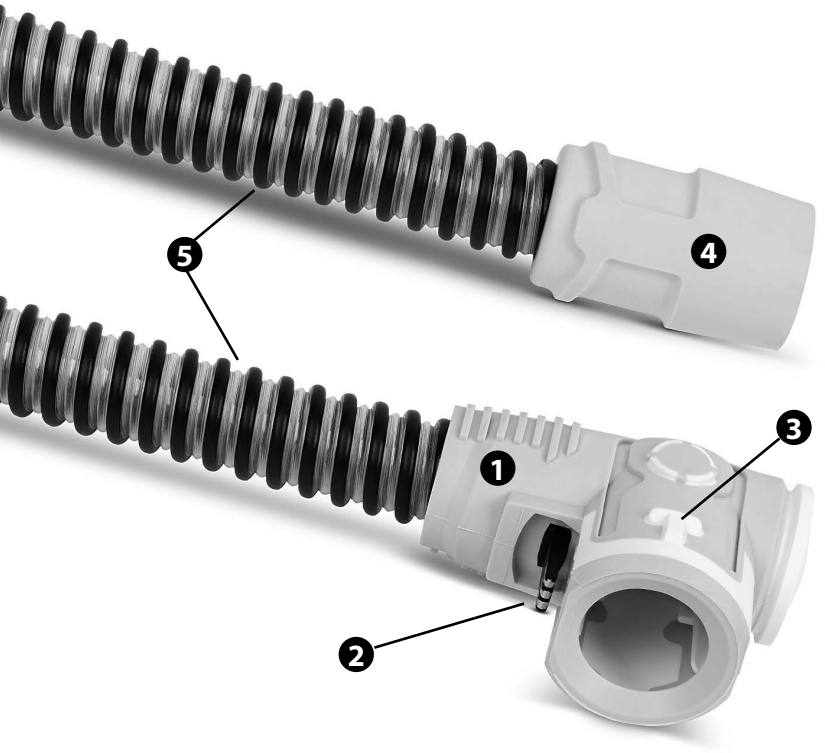

1.2 Indications For Use

The CPAP Heated Tubing is a heated wire breathing tube intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. It is indicated for home use, single-patient reuse. It may be used with non-invasive ventilation for adult patients. It is compatible with the ResMed AirSense™ 10 machines.

Federal law restricts this device to sale by or on the order of a physician.

1.3 ⚠ Warnings and Contra-Indications

- WARNING: This heated CPAP tube is a respiratory heated tube designed and validated for use with the ResMed AirSense™ 10 machines. Compatibility with other continous positive airway pressure (CPAP) machines has not been established. Do not use with other CPAP machines.
- WARNING: This heated CPAP tube used with parts that are not compatible with the device may degrade or interfere with the performance of the device.
- WARNING: This heated CPAP tube requires a mask to prevent asphyxiation and/or minimize rebreathing of carbon dioxide.
- WARNING: Compatibility of the heated CPAP tube, CPAP machine, and all the components necessary to connect the device prior to use is the responsibility of the customer.
- WARNING: Do not forcibly remove the connectors attaching the heated CPAP tube from the CPAP machine. Do not pull directly on the tubing to remove the heated tube from the CPAP machine. Always squeeze the release tabs to disconnect the heated tubing from the CPAP machine.
- WARNING: To avoid malfunction and disconnection of the heated CPAP tubing, ensure that components in use follow ISO 5367 or 80601-2-74 Standards. Noncompatible components could affect the heated tube performance.
- WARNING: Adding any unapproved attachments or accessories to the heated tubing may adversely affect the performance of the heated tubing, may cause the CPAP machine to not function as intended by the manufacturer and may reduce the quality of CPAP therapy or cause injury to the patient.
- WARNING: Inspect the device daily for integrity and wear and tear of the tubing. Inspect for holes, deforming of the tubing and any other form of damage and replace right away if you notice any damage.
- WARNING: Avoid operation of the heated tubing near heating sources such as lamps, electric blankets, heaters, etc. These additional heating sources can increase air temperature and interfere with the therapeutic process or cause harm to the patient.
- WARNING: Replace the heated tube every 90-days to prevent deterioration and or malfunction of the therapy. Using the heated CPAP tube beyond 90 days may result in reduced performance of the device or harm to the patient.
- WARNING: The heated CPAP tube is not compatible with sterilization processes.
- WARNING: The heated CPAP tube is designed to be used by one patient only to prevent cross-contamination and the spread of disease. Using the heated tubing on multiple patients may result in harm to the patient.
- WARNING: Avoid placing force or pressure on the heated CPAP tube that could compromise the performance and integrity of the device. Do not crush the tube. Damage to the heated CPAP tubing may result in decreased performance or harm to the patient.
- WARNING: Remove from use devices with physical damage such as tears, holes, kinks, exposed heating filaments, detached or missing components, or other damage that can potentially affect the device's structural integrity and performance. Attempts to repair or patch the device can compromise its performance and the safety of the patient. Do not attempt to repair heated tubing yourself if it is damaged.
- WARNING: Do not stack or combine with other equipment. This could jeopardize the

performance of the device or cause harm to the patient.

- WARNING: Follow cleaning instructions for the heated CPAP tube. Do not insert cleaning tools or other objects into the device to prevent damage which can compromise device performance.
- WARNING: Avoid using this device together with or on top of other devices, including electrical sources, as it could interfere with its performance; when such a setup is physician approved, it should be monitored closely to ensure performance is not compromised and that safety is maintained.
- WARNING: Follow equipment and device instructions to prevent changes in electromagnetic emission and decreased immunity. The use of additional wiring, transducers, and accessories with the validated standard setup recommended by the manufacturer could expose the patient to additional electromagnetic emissions and or decreased immunity resulting in improper function.
- WARNING: Maintain a 12 inch (30 cm) distance between auxiliary devices such as RF Communications devices (including antenna cables and external antennas) and any part of the heated CPAP tubing or manufacturer specified cables. Not following these instructions can lead to degradation of the performance of the heated tubing.
- WARNING: The heated CPAP tube is not compatible with MRI scanners.
- WARNING: Do not use this device if the room temperature is warmer than 35° C (95° F). If the device is used at room temperatures warmer than 35° C (95° F), the temperature of the airflow may exceed 41° C (106° F).
- CAUTION: Upon disposal of the heated CPAP tube, follow local government disposal laws. When permanently disposing, label the tubing as needed to prevent cross-contamination or use by another patient.
- CAUTION: The heated CPAP tube has been tested in accordance with appropriate standards for Radiated RF Emission levels so as to prevent electromagnetic interference and adverse effects to the patients and users of the heated tubing when used in accordance with the instructions. Modifications to the device could interfere with radio frequency and electromagnetic emission compliance and potentially harm the patient. As such, do not modify the heated CPAP tube.
- CAUTION: Patients in need of CPAP treatment have a higher tendency of being immune compromised increasing their likelihood of contracting respiratory diseases. Single patient use devices that are not replaced according to the manufacturer's instructions may be a potential source of infection. The device is to be kept patient- specific, replaced within the 90-day time limit, cleaned between uses, and maintained accordingly to minimize and prevent contaminants from exacerbating patients' health. Patient and hospital staff handling the device should follow aseptic protocols such as hand sanitizing, disinfection, and the use of disposable gloves to prevent additional sources of contamination prior to use and before and after the replacement of the device.
- CAUTION: This heated CPAP tube should be only air dried as listed in the cleaning instructions. The use of ovens, microwaves, heating equipment, or other mechanical devices could damage the performance and life of the device. Follow cleaning instructions provided in this user manual.
- CAUTION: Operators may include patients, home healthcare operators (non-patients assisting patients in home healthcare settings) and professionals in institutional healthcare settings. To avoid exposure to materials intended for trained professionals, patients and home healthcare operators should not perform cleaning and disinfection procedures intended for institutional operators.

2.0 USE AND CARE GUIDELINES

2.1 User Instructions

Instructions in section 2.1 are suitable for patients, home operators and institutional operators.

Remove the heated tubing from its original packaging and inspect for defects and integrity. In the event of damage contact the manufacturer for return and replacement. The device has two connection points, one to the mask and one to the equipment. The two connectors are linked by the heated flex tubing (see diagram below):

The heated tubing connector mechanism couples with the outlet port of the ResMed AirSense™ 10 machines. To connect the tubing, align the machine end fitting of the CPAP tubing to the CPAP machine air outlet port. Then press the CPAP tubing machine end fitting adapters to the mating portion of the CPAP machine air outlet connection.

Connect the heated tubing to the mask by aligning the mask end cuff to the mask port until the cuff is snug on the mask port. Review the device instructions. Test to ensure airflow through the tubing.

Proper placement and positioning of the mask is critical to the consistent operation of this equipment. Follow physicians and or therapist instructions on the use and placement of mask; and equipment/device instructions (Compatible Machines, Mask, and Heated Tube).

Disconnecting the heated tubing from the machine
Press the release mechanisms on the sides of the machine end fitting connected to the CPAP equipment and pull off the air outlet port to release the heated tube.

⚠ *In order to avoid leaks in the circuit, do not pull off from the machine by pulling directly the flex tubing. This action could damage to the device or impair the performance.*

2.2 Cleaning and Disinfection Instructions for the Heated Tubing

Clean heated tube before first use and daily while you are using the device.

2.2 Cleaning and Disinfection Process:

Instructions in section 2.2.1 are suitable for patients and home operators.
Home Cleaning Process:

1. Disconnect the heated CPAP tubing from the CPAP mask and your CPAP machine. Do not perform cleaning or disinfection processes on the tubing when in use.
2. Using warm tap water, rinse the inside and outside of the CPAP tubing thoroughly to remove excess soil. Rinse for approximately 60 seconds.
3. Fill your sink with warm water and mild unscented liquid dish soap (2-3 gallons). Immerse the heated CPAP tubing and connectors in the soap and water and gently agitate by hand for approximately one minute using a soft bristle brush to remove any soiling.
4. Rinse your heated CPAP tube with warm water thoroughly to remove all soap residue for approximately one minute.
5. Point the connector cuffs downward and gently tap the connector cuffs to remove excess water.
6. With the connectors/cuffs pointed downward, hang your tubing to dry.
7. Allow Heated CPAP tube to air dry thoroughly before your next use.

8. Visually inspect your heated CPAP tube to make sure it is clean. Repeat the cleaning process if it is not visibly clean.
9. Inspect your heated CPAP tube for damage or wear. Discard and replace if necessary.
10. Only reuse the heated CPAP tube when fully dry.

⚠ *Do not use harsh detergents, soaps, solvents, or alcohol to clean the heated CPAP Tube. Do not clean the Heated CPAP tube in a dishwashing machine, ultrasonic cleaner, or any other cleaning device not specified in the above instructions.*

Disinfection Process (Optional):
1. The home disinfection process is recommended for a maximum of 60 cycles.
2. Conduct the disinfection by immersing the heated CPAP tube at 75 ± 2°C (167 ± 4°F) bath of tap water for 30 minutes.
3. After disinfection, repeat steps 5-9 of the Home Cleaning Process outlined above before use.

Note: The maximum number of disinfection procedures for the heated CPAP tube is 60 cycles.

2.3 Troubleshooting: Consult your CPAP machine user manual.

3.0 SPECIFICATIONS / ADDITIONAL REQUIREMENTS

3.1 Storage and Transport Environment

Store and transport the device in its original package. The device packaging protects the device from sunlight damage, dirt, and other contaminants.
Storage and transport temperature range: -20° to 60°C (-4° to 140°F)
Storage and transport humidity range: 5% to 95% RH.

3.2 Operation Environment

Operating temperature range: 5° to 35°C (41° to 95°F)
Operating humidity range: 15% to 95% RH.
Operating atmospheric pressure: 1013 hPa to 738 hPa (0 to 2591 m / 0 to 8500 ft.)
Allow the device to acclimate to operating temperature for an hour or more before use if stored or transported outside of the operating temperature range.

3.3 Questions and Answers

Q. How frequently should I replace my heated tubing?
A. The heated tubing is to be replaced after 90-days or per physician instructions. Replace immediately in the event of damage such as leaks and/or faulty performance.

Q. Is this heated CPAP tube compatible?
A. Our heated tube is designed to be compatible with ResMed AirSense™ 10 machines only.

3.4 Part Replacement

Consult your doctor, respiratory therapist, or home health care provider in the event of device malfunction. The device use should not exceed 90-days.

3.5 Device Specifications

Components	Design
Heated tube hose length	6ft (1.83m)
ID (internal diameter)	15 mm
Flow resistance @30 l/min	≤ 0.04 hPa/l/m
Regulatory Compliance	ISO 5367:2014 ISO 18562-1 ISO 80601-2-70:2015 ISO 80601-2-74:2017
IP Rating	IP22 per IEC 60529: 2019
Device Compatibility with CPAP Equipment	ResMed AirSense™ 10 machines
ISO 80601-2-74	Humidifier class II
Maximum recommended working pressure	30 cmH_2O
Output Air Temperature	16° to 30°C (60° to 86°F) (typical operating conditions), < 41°C (106°F) Maximum
Tubing Compliance @60 hPa (cmH2O)	≤0.7 ml/hpa (ml/cmH2O)
Electrical Power	3.3Vdc, max. 0.5A

3.6 Warranty

This heated tube has a manufactures warranty of 30 days. This warranty is based on normal operating conditions of 8 hours per day.

3.7 Compliance with Standards

The heated tube complies with the requirements listed in the standards:

- ✓ IEC 60601-1 General Requirements for Basic Safety and Essential Performance of Medical Electrical Equipment.
  - Degree of Protection Against Electric Shock: Type BF Applied Part.
  - Degree of Protection against Ingress of Water: Drip Proof, IPx2.
  - Mode of Operation: Continuous.
- ✓ EN 60601-1-2 Electromagnetic Compatibility.
- ✓ ISO 80601-2-70 Sleep Apnea Breathing Therapy Equipment.
- ✓ ISO 80601-2-74 Respiratory humidifying equipment.
- ✓ ISO 18562 Parts 1-4 Biocompatibility evaluation of breathing gas pathways in healthcare applications.
- ✓ ISO 5367 Anaesthetic and respiratory equipment — Breathing sets and connectors.

3.8 Electromagnetic Compatibility

This heated CPAP tubing has been tested as detailed in the tables below with ResMed AirSense™ 10 machines and meets the emissions and immunity requirements of IEC 60601-1-2:2014/ AMD1:2020 when used as intended in Professional Healthcare Facility and Home Healthcare environments.

Standard compliance	Home Healthcare
CISPR 11	Group 1 Compliant
CISPR 11	Class B Compliant

Immunity Test	Compliance	
IEC 61000-4-2 per IEC 60601-1-2 (Immunity to Electrostatic Discharge)	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
IEC 61000-4-2 per IEC – 60601-1-2 Clause Table 5, 6, 7 and 8 (Immunity to Conducted Disturbances Induced by RF Fields)	3 V 0.15-80 mHz 80% AM at 1 kHz	6V ISM and Amateur Radio Bands 0.15-80 mHz 80% AM at 1 kHz

IEC 61000-4-3 per IEC 60601-1-2 (Immunity to Radiated RF Fields)	3 V/m 80 MHz-2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz-2,7 GHz 80% AM at 1 kHz
IEC 61000-4-8 per IEC 60601-1-2 (Power Frequency Magnetic Field)	30 A/m 50 Hz or 60 Hz	
IEC 61000-4-39 per IEC 60601-1-2 Clause 8.11 (Immunity to Proximity Magnetic Fields)	8 A/m at 30 kHz 65 A/m at 134.2 kHz, 7.5 A/m at 13.56 mHz.	

IEC 61000-4-3 per IEC 60601-1-2 Clause 8.10 (Proximity fields from RF wireless communication equipment, Immunity test levels)

Frequency (MHz)	Modulation	Immunity Level
385	Pulse Modulation: 18Hz	27 (V/m)
450	Pulse Modulation: 18Hz	28 (V/m)
710/745/780	Pulse Modulation: 217Hz	9 (V/m)
810/870/930	Pulse Modulation: 18Hz	28 (V/m)
1720/1845/1970	Pulse Modulation: 217Hz	28 (V/m)
2450	Pulse Modulation: 217Hz	28 (V/m)
5240/5500/5785	Pulse Modulation: 217Hz	9 (V/m)

3.9 Glossary of Symbols

Symbols	Description
	Attention, see product insert for additional details.
	See user instructions.
	Manufacturer Catalogue Number.
	Manufacturer unique batch or lot traceability identifier.
	Device manufacturer.

	Date of device manufacture.
Rx only	Device requiring prescription per federal law issued by a physician.
IP22	Protected from touch by fingers and objects greater than 12 millimeters. Protected from water spray less than 15 degrees from vertical.
	Keep away from direct sunlight.
	Temperature Limit *Indicates the temperature limits to which the medical device can be exposed.*
	Humidity Limitation *Indicates the range of humidity to which the medical device can be exposed.*
	Keep dry.
	Do not use it if the package is damaged.
	Not compatible with MRI scanner, maintain away from MR areas.
Standard Referenced: - ISO 15223-1:2021, Medical Symbols to be used with medical device labels, labeling, and information to be supplied - General requirements - IEC 60601-1, Medical electrical equipment - General requirements for basic safety and essential performance.	

Manufactured by:
Spirit Medical, Inc.
5000 Township Parkway
Saint Paul, MN 55110, USA

SpiritMedical.net
1-866-578-4889

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