

Operators Guide



Silenzio™

Silenzio® Plus

Silenzio® Delta

Declaration of Conformity Notice

This medical equipment complies with the Medical Device Directive, 93/42/EEC, and the following technical standards, to which conformity is declared:

IEC 601-1
IEC 601-1-2
ISO 9001
EN 46001
MDD-ANNEX II
NOTIFIED BODY: SEMKO

Type of Equipment: Nasal CPAP System

Trade name:	Silenzio,	Silenzio Plus,	Silenzio Delta
Model No.:	3351-00000	3361-00000	3331-00000

If you have any questions regarding the Declaration of Conformity for this product, please contact Nidek Medical Products, Inc.



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Silenzio, Silenzio Plus and Silenzio Delta Operators Guide

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INTRODUCTION

Silenzio is a lightweight, quiet and compact device used to treat Obstructive Sleep Apnea (OSA).

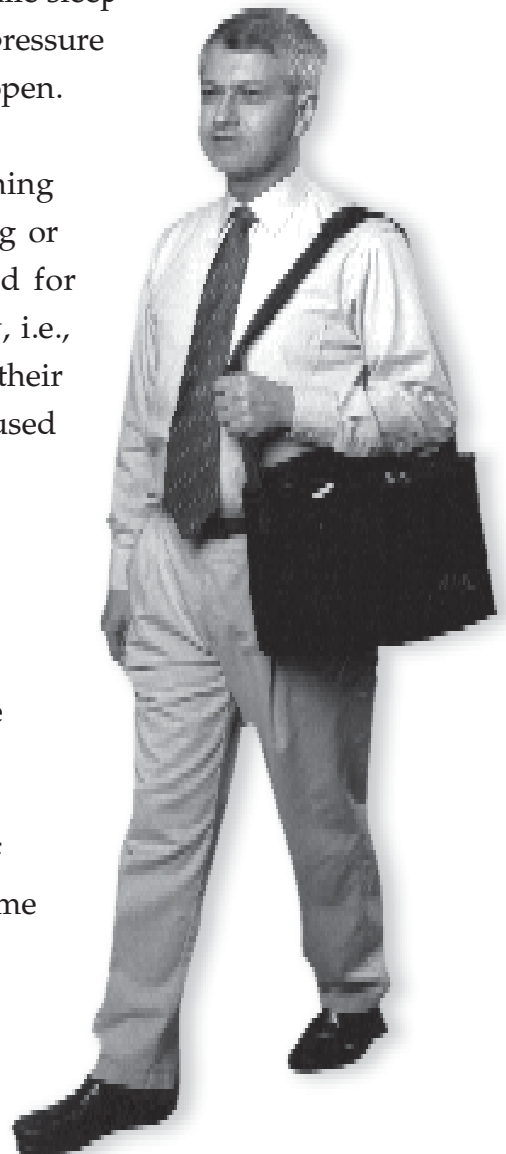
Obstructive Sleep Apnea (OSA) is a condition in which a person's airways become obstructed during sleep. The obstruction causes a temporary suspension of breathing, which may cause the patient to awake many times throughout a night, disturbing necessary sleep patterns.

Silenzio treats OSA by providing a positive pressure of air to the patient through a mask the patient wears while sleeping. This continuous positive airway pressure (CPAP) keeps the patient's airways open.

Silenzio is not a continuous breathing device. It is not capable of restoring or sustaining life. **Silenzio** is intended for spontaneously breathing adults only, i.e., adults who can breathe normally on their own during waking hours. It is to be used only under the advice of a physician.











Silenzio is safe, easy to use and equipped with a built-in universal power supply which automatically adapts to any voltage throughout the world.

To make sure **Silenzio** gives years of trouble-free operation, please take time to carefully read the *IMPORTANT SAFEGUARDS* section on the following pages.



Equipment Symbols

The following symbols appear on the Silenzio Nasal CPAP system.

Symbol	Compliance	Meaning
	IEC 878 Symbol #03-02	:This symbol indicates ATTENTION, consult the ACCOMPANYING DOCUMENTS.
	IEC 417 Symbol #5172	:This symbol indicates Class II equipment.
	IEC 878	:This symbol indicates the "ON" condition and connects the equipment to the MAINS supply.
	IEC 878	:This symbol indicates the OFF condition and disconnects the equipment from the MAINS supply.
	IEC 878	:This symbol indicates TYPE BF equipment.
	IEC 878 Symbol #01-14	:This symbol indicates equipment suitable for alternating current.
EPAP	Symbol	:Expiratory Pressure
IPAP	Symbol	:Inspiratory Pressure
	Symbol	:Indicates conformity with the directive 93/92/CEE certified by the notified body no. 0413.
C - H	Symbol	:Hour Meter Status; Compliance Hours - Total Hours.
	Symbol	:Progressive rise in pressure (pressure ramp).
	Symbol	:Progressive rise in pressure reset to zero.
	Symbol	:When lit, pressure = set pressure.
Freq. (c/min)	Symbol	:Minimum Respiratory Frequency.

IMPORTANT SAFEGUARDS



WARNING - Do not operate in the presence of anesthetic gases. Explosion Hazard.



WARNING - The patient must be able to breathe spontaneously under CPAP treatment or in the event of an interruption of CPAP therapy (e.g.) power failure, tube disconnect or kinked tubing.



AVOID RISK of ELECTRIC SHOCK - Always unplug Silenzio before cleaning it. Avoid overloading wall outlets and extension cords, which creates a fire hazard and risks electric shock.



CONTROLS and SETTINGS - *Never try to adjust Silenzio.* Settings are fixed according to medical prescription. Only a doctor or respiratory therapist is authorized to adjust Silenzio controls and settings.



CONNECTIONS - Turn Silenzio OFF before connecting or disconnecting any attachments or accessories. Turn Silenzio OFF before unplugging.



HEAT, SPARKS and FLAMES - Keep Silenzio away from any source of sparks or heat. If your doctor has prescribed supplementary oxygen, be aware that, while oxygen is not combustible, it activates the combustion of flammable material. Keep ignitable materials away from the equipment and oxygen tubes. Keep Silenzio at least 6 feet from any flame, such as stove, water heater, fireplace, etc.



WATER and MOISTURE - Avoid placing containers of liquid on top of Silenzio. Spilled liquid can result in electrical shock. Do not immerse Silenzio into water or any other liquid. Do not place Silenzio where it can fall into water, such as near a bathtub, toilet, sink, wash bowl, laundry tub, swimming pool, etc. Do not touch Silenzio if it has fallen into water! Unplug it immediately. Do not use Silenzio in a room with a high moisture content, such as a wet basement. To properly clean Silenzio, refer to the *CLEANING* and *DISINFECTING* section of this Owner's Guide.

IMPORTANT SAFEGUARDS



SERVICE - Never remove Silenzio's protective cover. Do not grease or oil any part of Silenzio. If Silenzio does not operate normally, or if the power cord or plug has damage, refer servicing to your Silenzio dealer or Authorized Nidek Medical Repair Center.



VENTILATION - Allow good circulation of air around Silenzio. Do not place Silenzio against a wall or curtain or on a bed, blanket, sofa or other similar surfaces. Do not operate Silenzio in a closed space such as a drawer, or built-in bookcase.



SOLVENTS - Do not spray aerosols near Silenzio, even if the unit is off. Do not open containers of solvents such as mineral spirits or alcohol while Silenzio is being used.



SMOKING - Do not allow smoking in the room where Silenzio is being used.



EXTREME TEMPERATURES - During transport, storage or use, avoid submitting Silenzio to high or low temperatures. Silenzio should be at room temperature before switching ON. The air flow produced by Silenzio for breathing can be as much as 10°F higher than the temperature of the room. Caution should be exercised if the room temperature is warmer than 90°F.



TRANSPORT - Place Silenzio in its carrying case before transporting. If travelling by air, carry Silenzio as personal luggage. Never allow Silenzio to be handled as general luggage.

UNPACKING YOUR SILENZIO

CONTENTS

As you unpack your SILENZIO, please make sure the following items are included:

SILENZIO and SILENZIO PLUS

- 1- 6 ft. corrugated Patient Circuit Tube with connector
- Carrying Case

SILENZIO DELTA

- 1- 6 ft. corrugated Patient Circuit Tube with connector
- 1- Pressure Sensing Tube
- Carrying Case

ACCESSORIES

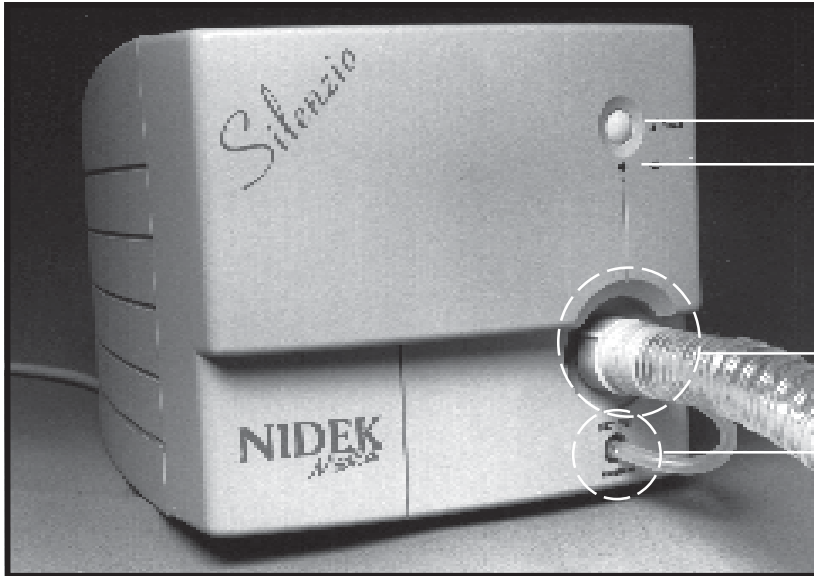
Various accessories are available for use with Silenzio.

They include:

- Mask (with connector) (required)
- Headgear (required)
- Supplemental Oxygen Administration Kit. (Part #9003-1901)
- Replacement Air Filters (Part #9003-6637)
- Optional Electrostatic Filters (Part #9003-6638)
- DC to AC Converter (Part #9003-1900)
- Humidification Starter Kit System (Part #9003-1910)
- Humidification Heater Base (Part #9003-1911)
- Humidification Administration Kit (Part #9003-1902)

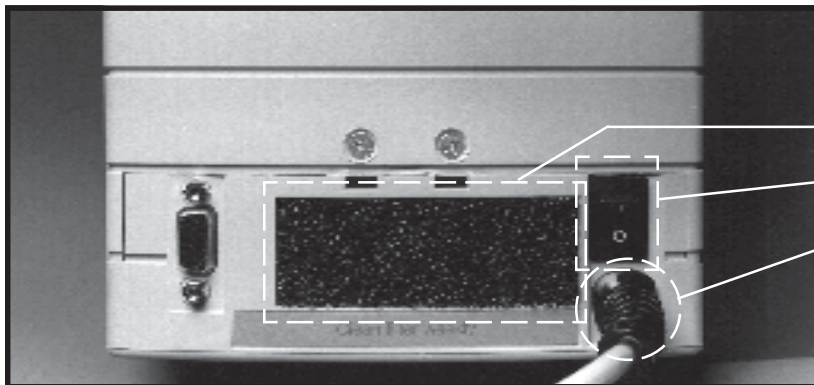
Important: Silenzio should only be used with masks (and connectors), headgears, supplemental oxygen kits and air filters recommended by the manufacturer of Silenzio, or by your physician or respiratory therapist.

BUTTONS AND FUNCTIONS



FRONT

- ❶ Patient's Ramp Reset Button
- ❷ Pressure Leakage Indicator
- ❸ Patient Circuit Connection
- ❹ Patient Pressure Sensing Connection (*Delta Model Only*)



REAR

- ❺ Air Filter
- ❻ On(i)/Off(0) Switch
- ❼ Power Cord

OPERATING INSTRUCTIONS

The following instructions use numbers as well as names to help you find buttons and features on your Silenzio unit. For example, to locate numbered items ❶, ❷ or ❸ on your Silenzio, refer to the *BUTTONS and FUNCTIONS* section of this Owner's Guide.

SETTING UP

1. Place Silenzio in a well-ventilated area, away from walls, curtains, blankets, etc. Be sure the air filter ❸, on the rear of Silenzio, is not blocked.

2. Make sure Silenzio is unplugged. Turn the On/Off switch ❹ to the OFF (0) position before making connections.

GETTING STARTED

3. Insert the Patient Circuit connector into the large Patient Circuit Connection ❺ on the front of Silenzio.

4. *(For Delta Model Only)* Attach the smaller tube, which leads from the Patient Circuit connector, to the Patient Sensing Connector ❻ on the front of Silenzio. Turn the Patient Circuit connector so that the smaller tube is not kinked or pinched.

5. Connect your mask to the opposite end of the Patient Circuit until it is secure. Use only a mask (and connector) recommended by the manufacturer of Silenzio, your physician or therapist.

GETTING STARTED

6. Fit your headgear on your head and the mask over your nose. A tight fit is not necessary. If your mask has been properly fitted, the size and style should provide a comfortable fit and efficient air seal.

7. With Silenzio OFF (0), plug Silenzio's power cord ❶ into your electrical outlet.

8. Turn Silenzio ON (I) ❷.

9. Take your time to get used to the air pressure felt in the mask. With your mouth closed, take a few deep breaths to help you adjust to breathing against the air pressure.

10. Your mask, and/or connector, will have at least one vent hole to allow your exhaled (CO₂) to escape. Be sure the vent hole(s) are not blocked.

11a. With the mask and the headgear in place, check the Pressure Leakage Indicator ❸. A green light indicates there are no significant leaks in the mask, Patient Circuit or connections. If the Pressure Leakage Indicator ❸ does not show green, adjust your mask and/or headgear until the green light illuminates. Silenzio will now provide the appropriate prescription pressure.

Silenzio Models Only

11b. With the mask and the headgear in place, hold down the Patient Ramp Reset Button and check the Pressure Leakage Indicator ❸. A green light indicates there are no significant leaks in the mask, Patient Circuit or connections. Release the Patient's Ramp Reset Button. If the Pressure Leakage Indicator ❸ does not show green, adjust your mask and/or headgear until the green light illuminates. Silenzio will now provide the appropriate prescription pressure.

Silenzio Delta and Plus Models Only

OPERATING INSTRUCTIONS

12. Your doctor or respiratory therapist may set the Ramp Selection Control to provide more comfort during the time before you fall asleep. If so, the pressure will gradually build to the prescribed pressure over the time period set on the Ramp Control. (*Silenzio Model*) - to activate the ramp you must press the Patient Ramp Reset Button ❶ on the front of Silenzio. (*Silenzio Plus and Silenzio Delta Model*) - unit will automatically ramp if ramp is set and unit is turned on.

13. If you take longer than usual to fall asleep, or if you wake up in the night and wish to restart the ramp phase, press and release the Patient Ramp Reset Button ❶ on the front of Silenzio.

SAFE SETTINGS

14. Your doctor will have prescribed a Silenzio pressure setting specific to your needs. Silenzio is designed to help you get a good night's sleep. If you have a problem obtaining comfort using Silenzio, consult your doctor.

15. If your doctor has prescribed supplemental oxygen for use with Silenzio, follow the doctor's or therapist's instructions.

WHEN YOU HAVE FINISHED

16. Before turning Silenzio OFF (0), remove your mask and headgear and, if you are using supplemental oxygen, turn the oxygen source OFF.

Warning: *Never use your mask while Silenzio is turned OFF (0). Silenzio must be ON (I) and operating properly to provide new air to flush the air you exhale (CO₂) out of the mask through the vent hole(s). If Silenzio is OFF (0), is operating improperly or is operated at low pressure, CO₂ may accumulate in the mask and circuit tubing. Breathing CO₂ for several minutes can, in some circumstances, lead to suffocation.*

Warning: *A supplemental oxygen source, if one is used, must always be turned OFF when Silenzio is OFF (0). If oxygen is left on while Silenzio is not operating, oxygen may accumulate in the mask or mask connector and create a risk of fire.*

TURNING SILENZIO OFF

17. After you have removed the mask and turned OFF your oxygen (if used), turn Silenzio OFF (0).

18. Unplug Silenzio before detaching Patient Circuit, mask and oxygen tubing.

19. Refer to daily cleaning instructions in the *CLEANING and DISINFECTING* section of this Owner's Guide.

CLEANING AND DISINFECTING

Regular cleaning is important for the proper operation of Silenzio. All cleaning and disinfecting can be done by the patient.

BEFORE CLEANING

Always take the following steps and precautions before cleaning Silenzio parts and accessories:

1. Turn OFF (0) Silenzio.

DAILY (After each use)

2. Clean the mask by wiping the inside and outside of the mask with a soft cloth and warm soapy water. Carefully rinse the mask with clean water and dry with a dry cloth. Store mask in a dry, dust-free environment when not in use.

WEEKLY

3. Remove the air filter ⑤ from the rear of the Silenzio unit. Wash the air filter with warm, soapy water, rinse in running water and allow to completely dry before replacing it on your Silenzio unit.

4. Unplug Silenzio.

5. To clean your Silenzio unit, wipe it with a clean, soft cloth dampened with warm, soapy water. Then, wipe the unit with a cloth moistened only with water. Allow Silenzio to completely dry before plugging in the Power Cord ⑦.

IMPORTANT

Never immerse your Silenzio unit in water! Take special care to prevent moisture from entering the unit.


6. To clean the Patient Circuit, remove the connector from the Patient Circuit. *(Delta Model Only) Then remove the smaller tubing (pressure sensing tube) found inside the Patient Circuit.* Immerse **only** the Patient Circuit in warm, soapy water. Use a disinfecting solution on the Patient Circuit, if necessary. Rinse the Patient Circuit thoroughly in clean water.

7. Allow the Patient Circuit to completely dry before reassembling.

CAUTION

Do not use abrasive powders or solvents, such as alcohol or acetone, to clean Silenzio parts or accessories.

MAINTENANCE

- ✓ Silenzio operates without the need for outside service, maintenance or repair, provided that you follow all safety, operating, and maintenance instructions. Please retain this Owner's Guide for future reference. The maintenance recommendations listed below are for your convenience.
- ✓ **FILTER REPLACEMENT**
It is recommended that you replace the Air Filter  on the rear of the Silenzio at least every 6 months. Obtain replacement filters from your Silenzio dealer.
- ✓ **MASK REPLACEMENT**
Replace the mask when it begins to lose its flexibility or shows excessive wear.
- ✓ **ANNUAL INSPECTIONS**
Have your physician, respiratory therapist or Silenzio dealer check your unit once a year to ensure proper operation.
- ✓ **MAINTENANCE RECORD**

Date	Time Meter Reading	Filter Replacements	Mask Replacements	Pressure Setting Inspections

PHYSICIAN INFORMATION

Physician: _____

Telephone: _____

Prescription: _____

SILENZIO DEALER INFORMATION

Dealer: _____

Contact: _____

Telephone: _____

TROUBLE SHOOTING

Problem	Probable Cause	Possible Solution
Unit will not function with the switch in the ON (I) position.	<ul style="list-style-type: none"> • No power. 	<ul style="list-style-type: none"> • Check power cord. • Check wall outlet.
Will not supply a flow of air.	<ul style="list-style-type: none"> • Blower fault. • Blocked sensing tube. <i>(Delta Model Only)</i> • Electronic fault. 	<ul style="list-style-type: none"> • Contact Silenzio dealer. • Check sensing tube <i>(Delta Model Only)</i> • Contact Silenzio dealer.
The blower is revolving at maximum speed.	<ul style="list-style-type: none"> • Excessive leak in Patient Circuit. • Unconnected Sensing tube. <i>(Delta Model Only)</i> • Electronic fault. 	<ul style="list-style-type: none"> • Check connections and seal of mask. • Check connections. • Contact Silenzio dealer.
Unit will not supply the prescribed pressure.	<ul style="list-style-type: none"> • Ramp is activated. • Air filter is blocked. • Faulty operation. • Incorrect pressure setting. 	<ul style="list-style-type: none"> • Wear mask. Wait for full pressure build-up or press and hold down the Patient Ramp Reset Button on the front of the unit to verify pressure. • Check that air filter is in place and clean. • Contact Silenzio dealer. • Contact Silenzio dealer.

SPECIFICATIONS

PRINCIPLE OF OPERATION

Silenzio's primary component is a turbine blower driven by a brushless DC electric motor. The speed of the motor varies depending upon voltage applied. An electronic device regulates the speed of the motor according to the amount of pressure required in the Patient Circuit.

SAFETY

Silenzio is manufactured to respect international standards defining double insulation characteristics, and is protected by a fuse. In the unlikely event of a failure in the command electronics, Silenzio will be **unable** to deliver pressure greater than 22 cm H O.

Automatic Universal Power Supply

SPECIFICATIONS

90-250 V ~ 50/60 Hz

Fuse 3.2 AMP

80 VA maximum

Insulation Class II (double insulated) 2

Noise Level

< 32 dBA at 1 meter with a setting of 10 cm H O pressure (mask sealed).

Dimensions

6.6"H x 7.3"W x 10.3"D

16.8 cm H x 18.5 cm W x 26.2 cm D

Weight

6 lbs.

2.7kg.

Manufacturer will send, upon request, wiring diagrams, component lists, or other technical information which may be useful to an authorized technician repairing parts of Silenzio that the manufacturer has designated as being repairable.

MORE INFORMATION

Silenzio

Nidek Medical Products, Inc. warrants to the original dealer-purchaser of a Nidek Medical Silenzio that it shall: 1) Conform to Nidek Medical's specifications, subject to ANSI tolerances, at the time of manufacture and 2) be free of defects in material and workmanship for a period of three (3) years on Silenzio, (2) years on Silenzio Plus and (1) year on Silenzio Delta.

To make a claim under this warranty, the Purchaser must: 1) Give Nidek Medical written notice of the breach of warranty, within ten (10) days after discovery of such breach, 2) immediately upon discovery of the claimed breach discontinue all use of the Silenzio; and 3) upon the request of Nidek Medical, return the Silenzio or the applicable component part, freight prepaid, to Nidek Medical's plant of manufacture or such other location as designated by Nidek Medical. If it is determined by Nidek Medical that the Silenzio or the applicable component is in breach of warranty, Nidek Medical, at its option, will repair or replace it without charge.

The cost of returning the Silenzio or component part to the Purchaser after repair or replacement will be paid by Nidek Medical. If, however, any Silenzio or component part returned by the Purchaser because of an alleged breach of warranty is found by Nidek Medical not to be in breach of warranty, then the Silenzio or component part will be returned to the Purchaser, shipping charges collect, and the Purchaser agrees to pay a service charge to Nidek Medical to cover the cost of handling and testing the Silenzio or component part. Dealer labor costs for removal and replacement of parts under warranty are not covered and are the responsibility of the dealer.

This warranty is void if the Silenzio or any component part thereof has been damaged by accident, abuse, misuse, neglect, alteration, improper service, repair by other than authorized personnel or other causes not arising out of defects in material or workmanship. Wear of components in normal operation, and failures resulting therefrom as determined by Nidek Medical, are excluded from this warranty.

This warranty is not assignable by the Purchaser.

NIDEK MEDICAL MAKES NO OTHER WARRANTIES OF ANY KIND WHATSOEVER, EXPRESSED OR IMPLIED, WITH RESPECT TO THE SILENZIO CPAP OR ITS COMPONENT PARTS AND ALL IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY EXPRESSLY DISCLAIMED AND EXCLUDED BY NIDEK MEDICAL. Nidek Medical's exclusive liability with respect to the Silenzio shall be to repair (at Nidek Medical's sole option) the Silenzio or any of its component parts that prove to be defective in materials or workmanship during the warranty period. Normal maintenance required during the warranty period is not included in this warranty. No claim of any kind whatsoever against Nidek Medical with respect to the Silenzio or its component parts whether or not based in contract, warranty, negligence, strict liability in tort, or any other theory of law, shall be greater in amount than the purchase price of the Silenzio. Without limiting the generality of any of the foregoing, Nidek Medical shall in no event be liable for any special, indirect, incidental, or consequential damages.

NIDEK
Medical

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