PHILIPS

InnoSpire Go
イノスパイア ゴー

the Oxygen Concentrator supplies shop

InnoSpire Go

Mesh nebulizer system

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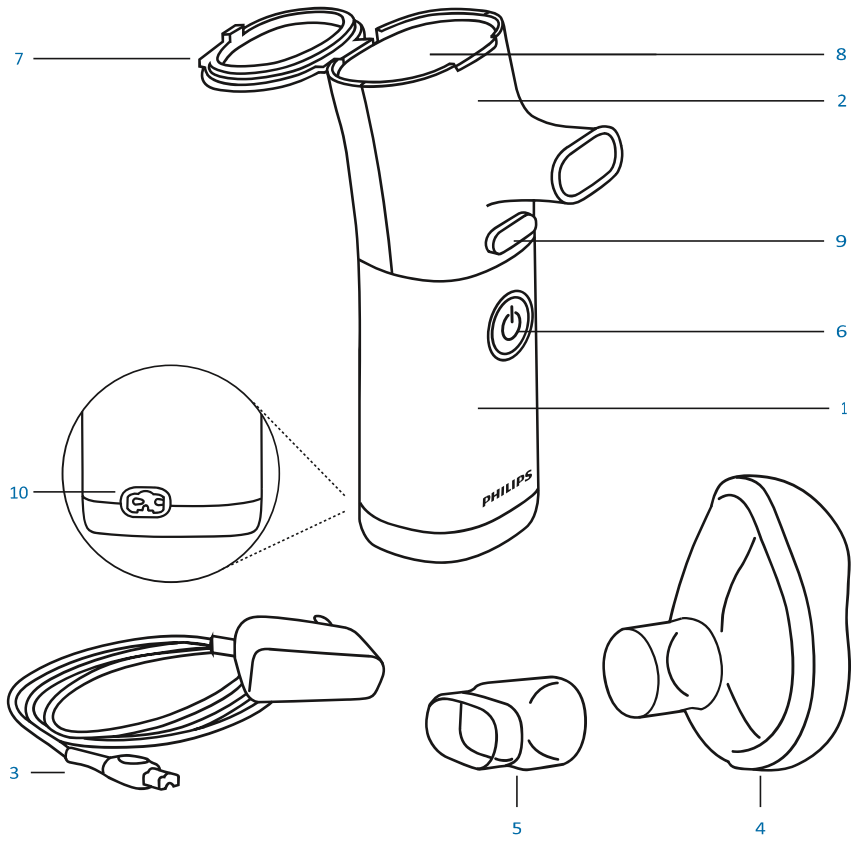


1. Handset
2. Mouthpiece assembly
3. AC power adapter
4. LiteTouch medium mask (age 2 - 5 years)
5. Mask adapter
6. On/Off button and LED indicator
7. Medication chamber lid
8. Medication chamber
9. Mouthpiece assembly release button
10. Power socket (back view)
11. Carry case (not shown)

Instructions for use

Please read these instructions carefully before first use. If you do not understand any portion of these instructions, contact your healthcare provider or call Philips Customer Service at 1-724-387-4000.

General information

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or licensed healthcare professional.

Intended use: The InnoSpire Go is a vibrating mesh nebulizer system designed to aerosolize liquid medications for inhalation by the patient. The device may be used with pediatric (2 years and older), defined by the prescribed medication, and adult patients in the home environment or in a hospital/clinic setting.

⚠Keep these Instructions for future reference

Retain carton and packing materials for storing the unit or for product returns.

⚠Cautions

It is recommended to have a backup device (e.g. MDI) for respiratory delivery in case a situation arises when your nebulizer cannot be used.

- InnoSpire Go is intended for SINGLE PATIENT USE, to deliver multiple doses.
- It is not to be used by patients that are unconscious or not breathing spontaneously.
- The patient or the patient's care giver is the intended operator of the device.
- Only use this nebulizer with medications prescribed by your physician.
- Do not place or store the product where it can fall into water.
- Do not submerge the handset in water or other liquid cleaning agents.
- If the handset is accidentally dropped into a liquid, immediately disconnect the AC adapter from the wall outlet, prior to removing the handset from the liquid.
- Any liquid spilled on the handset should be allowed to dry before operating.
- Do not position the product where it is difficult to disconnect the plug.
- Adult supervision is necessary when this product is used by, on, or near children or physically challenged individuals or individuals with learning difficulties.

- Use this product only for its intended use as described in this manual. Failure to do so may compromise performance. Only use accessories provided with the nebulizer and recommended by the manufacturer. Store in a clean place out of the reach of children.
- Do not disassemble or modify the nebulizer in anyway. There are no serviceable parts. The battery is non-replaceable.
- The battery has been fitted at the date indicated on the unit carton and has a shelf life of 18 months past this date.
- Never charge or operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water.
- Do not connect to other equipment not described in these instructions.
- Do not charge your device on an aircraft.
- Keep the power cord away from heated surfaces.
- The nebulizer must be operated using the specified power sources.
- Always check the inside of the mouthpiece assembly or mask for any debris before use.
- Do not use while operating a vehicle.
- Never use when lying down.
- When operated at an ambient temperature 40˚C/104˚F the handset can reach temperatures of up to 43˚C/109˚F. The device should not be used for more than 10 minutes during this scenario.
- Do not use in an anesthetic or ventilator breathing system.

- InnoSpire Go and all its parts (including battery) must be disposed of properly and according to the local regulations in force (for example the WEEE directive).
- Small parts can be inhaled or swallowed. In addition, the cable, due to its length, may result in provoking strangulation or asphyxiation. Do not leave the device alone with a small child or physically challenged individual or individual with learning difficulties.
- The nebulizer should not be used around flammable substances e.g. oxygen, nitrous oxide, or in the presence of a flammable anesthetic mixture.
- Never poke the mesh, or clean it with any sharp objects. This could damage the mesh and prevent your device from operating properly.
- Do not autoclave the device.
- Report unexpected operation or events to Philips.
- Precautions are to be taken in the event of changes in the performance of the device, please refer to the troubleshooting section.

How to use your InnoSpire Go

1. After unpacking the nebulizer check you have all the items listed and that there is no visible damage or defects. Contact your product distributor or Philips customer service if anything is missing or damaged.
2. Prior to first use clean the mouthpiece assembly as per the cleaning instructions and fully charge the battery. Ensure the device is disconnected from the power during assembly and disassembly.
3. Check the nebulizer and accessories are clean (free of debris), dry and not damaged prior to use.
4. Attach the mouthpiece assembly to the handset. Do not use separate mask adapter as a mouthpiece.
5. Lift the green medication chamber lid.
6. Empty the contents of the medication vial into the medication chamber.
   - The maximum fill volume is 8ml and this is shown by the word MAX on the protrusion below the hinge. **Do not fill medication above this level.**
7. Close the lid to the medication chamber.
8. If using a mask, attach the mask adapter to the mouthpiece assembly and attach the mask to mask adapter.
9. If you are using the power adapter to power the nebulizer, plug the cable into the socket on the handset and plug the adapter into the wall outlet.
10. Press the on/off button on the handset to switch the nebulizer on and begin nebulization.

Check the battery level.

- If the LED is **SOLID GREEN** the battery is charged.
- If the LED is **SOLID AMBER**, there is enough charge for at least one more treatment. Please charge your nebulizer after your treatment.
- If the LED **FLASHES AMBER** and then switches off there is not enough charge to take a treatment.

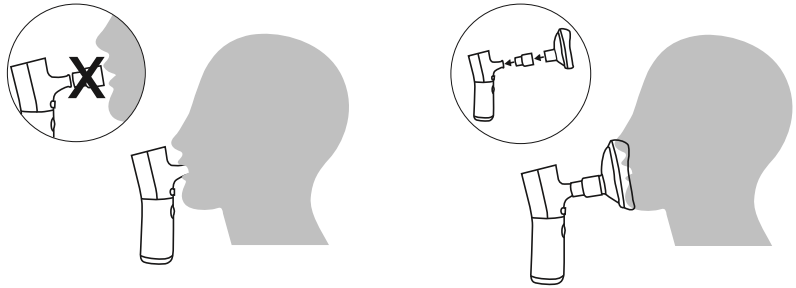
- If the LED does not illuminate, please refer to the troubleshooting section of this manual.

Ensure aerosol is coming out of the mouthpiece assembly or mask.

12a) **If using the mouthpiece,** hold the handset in your hand and place the mouthpiece between your teeth with your lips sealed around it. Breathe normally through your mouth.

b) If using a mask, hold the handset in your hand and gently press the mask against your face and breathe normally through your mouth.

During use, some aerosol will be emitted from the back of the mouthpiece assembly.



Do not tilt the device in any direction more than 45 degrees during the course of a treatment as this will prevent the nebulizer from completely nebulizing all the medication in the chamber.

If you need to take a rest, press the on/off button to stop your treatment. To continue your treatment press the on/off button again.

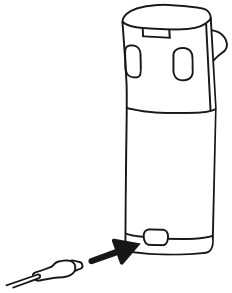
Your treatment is finished when the nebulizer beeps and the LED flashes. The device will turn off automatically.

Check the medication chamber for residual medication. If there are more than a few drops remaining, press the on/off button again to continue your treatment.

Clean the nebulizer following the cleaning instructions.

Charging the battery

1. Connect the power adapter to the socket on the back of the handset.
2. Plug the other end of the power adapter into the wall outlet.
3. The LED will **PULSE GREEN**.
4. Charge the battery until the LED turns **SOLID GREEN** indicating it is fully charged.
5. Unplug the power adapter from both the handset and the wall outlet. It is recommended to unplug the power adapter once the battery is fully charged to preserve battery life.



Cleaning and maintenance

⚠Cautions

- **Do not autoclave the mouthpiece assembly or handset.**
- **Do not put any part of the device in a microwave or conventional oven.**
- **Do not immerse the handset in liquid or steam clean.**
- **Never poke or clean the mesh with any sharp objects as this will damage the mesh.**
- **Do not clean the device when in use.**
- **Disconnect device from power supply prior to cleaning.**

Cleaning: home environment and hospital/clinic setting

After each use:

- Pour away residual medication from the medication chamber.
- Press the mouthpiece assembly release button to separate the mouthpiece assembly from the handset.
- Rinse the mouthpiece assembly thoroughly under running tap water.
- Shake off excess water and allow to air dry fully before storing.

Daily cleaning

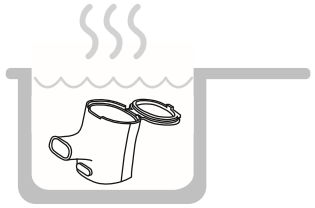
- Wash the mouthpiece assembly by hand in a bowl of warm soapy water (liquid dishwashing soap) for 2 minutes.
- Rinse the mouthpiece assembly thoroughly under running tap water.
- Shake off excess water and allow to air dry fully before storing.

Weekly disinfection

CAUTION: Risk of scalding. Use care around boiling water and in handling hot parts.

- Prior to disinfection, ensure all parts are visibly clean and free from dirt/debris.

  Boil the mouthpiece assembly in water for 10 minutes. Ensure the medication chamber lid is open and there is enough water in the pan to prevent the mouthpiece assembly from touching the bottom or boiling dry. Shake off excess water and allow to air dry fully before storing.



Or

- Immerse the mouthpiece assembly in a disinfectant of the Gluteraldehyde group (testing performed with Korsolex Extra, 4% for 15 minutes). Rinse thoroughly according to manufacturers instructions.

Mask cleaning

- Wipe your handset clean with a clean damp cloth weekly or as needed. Do not use other cleaning methods or solutions.

Handset cleaning

- If using a mask and mask adapter, once a week: agitate for 2 minutes or soak for 10 minutes, in warm soapy water (liquid dishwashing soap), rinse thoroughly under running tap water and air dry fully.
- After each cleaning procedure visually inspect for any remaining dirt/debris, if any remains repeat the procedure. Visually inspect for any moisture before storing.

Maintenance

Mouthpiece assembly can be cleaned (boiled/disinfected) up to 52 times over 12 months.

To keep your InnoSpire Go working at the optimum level you should replace the mouthpiece assembly and mask, if used, every 12 months as this is a consumable part.

LED Indication

LED Indication	What it means
SOLID GREEN	The battery is charged
SOLID AMBER	There is enough charge for at least one more treatment
FLASHES AMBER FIVE TIMES	There is not enough charge to take a treatment
FLASHES GREEN OR AMBER FIVE TIMES	The treatment is finished
PULSES GREEN	The battery is being charged

Troubleshooting

Problems	Solutions
The on button is pressed but nothing happens (no light, no nebulization).	Battery has insufficient charge, follow battery charging instructions. If the problem persists, contact your customer services representative.
LED illuminates on button press but goes off when button released.	Check to ensure that the mouthpiece assembly is attached properly. Make sure that the contacts on the handset are dry and free of debris. Make sure that there is medication loaded in the chamber. Recharge the battery.
When charging the battery, the LED does not pulse or turn on.	Ensure that the power cable is connected to the handset and plugged into the wall outlet or disconnect the power supply and reconnect.
Treatments take longer than usual with the same mouthpiece assembly.	Boil the mouthpiece assembly as per the weekly disinfection instructions.
Device indicates end of treatment but medication remains in medication chamber (more than a few drops).	Ensure nebulizer is held upright during nebulization. If the problem persists, contact your customer services representative.
Device does not indicate end of treatment even though all medication is nebulized.	Contact your customer services representative.

Should the device still not operate properly after checking the unit as indicated above it may have a critical error, contact Philips Customer Service at 1-800-345-6443 or 1-724-387-4000.

Technical specifications

Mains power supply	Input = 100 – 240 V~, 50/60 Hz Output = 5V ⎓, 1.0A
Internal rechargeable battery power supply (lithium polymer)	3.7 Volts nominal, 1200 mAh
Weight	0.29 lbs/111g
Size	2.76" x 1.77" x 5.31" / 7.0cm x 4.5cm x 13.5cm

Class II device internally powered device (double safety insulation)
Type BF device (device with specific protection against electrical hazards)
Ingress Protection rating IP22. (Protected against solid foreign objects of 12.5mm diameter and greater; protected against vertically falling water drops when device titled up to 15°) The InnoSpire Go handset and charger form a Medical Electrical System, in which the charger is not Medical Electrical Equipment. The IP22 rating applies to the InnoSpire Go handset, the charger rating is IPX0.
All components shown in the illustration are applied parts.
Materials: Handset - Polyamide (PA) and Thermoplastic elastomer (TPE),
Mouthpiece Assembly - Polyamide (PA) and Polypropylene (PP)

Certification

Reference to standards
Electric safety standards EN 60601-1
Electromagnetic compatibility according to EN 60601-1-2

Operating conditions

Temperature range of 41° F – 104° F /+ 5 °C to + 40 °C
Humidity range of 15% RH to 93% RH, non-condensing Atmospheric pressure 70 kPa to 106 kPa

Storage and transport conditions

Temperature range of MIN -13° F MAX +158° F / MIN -25° C MAX +70° C
Humidity range of MIN 10% RH –MAX 93% RH Atmospheric pressure 50 kPa to 106 kPa

Replacement parts and optional accessories

Adult mask - large (ages 5 years plus)	1127875
Pediatric mask - medium (ages 2 - 5 years)	1127798
Mask adapter	1125985
Mouthpiece assembly	1128501
Plug adapter	1127651
Carry case	1128576

Technical data EN13544-1

Aerosol output	1.19 mL
Aerosol output rate	0.26 mL/min
Max fill volume	8 ml
Max medication temperature increase at max fill	<10°C above ambient temperature
Noise level	<35dB at 1m
Percentage of fill volume (2.5 mL) as aerosol output (delivered to filter) in one minute	10.2%
Residual volume	0.30 mL

If the device has been stored at the extremes of the storage temperature, please allow at least 1 hour at room temperature before using the device.

This table summarizes the performance with the mouthpiece and with a face mask when nebulizing salbutamol (5 mg/2.5 mL). Values reported are mean and 95% confidence interval. When used with a face mask the performance can be less and you may need to consult your physician about the treatment frequency and length of treatment.

Parameter	InnoSpire Go	InnoSpire Go with adult LiteTouch face mask
Mass median aerodynamic diameter (MMAD)	3.99 µm ± 0.73	4.18 µm ± 0.78
Fine particle fraction <5 µm	64.4% ± 12.2	61.3 ± 12.4
Respirable fraction 1 - 5 µm	62.7% ± 11.6	59.7% ± 12.0
Delivered dose	1.19 mL ± 0.06	0.87 mL ± 0.06
Respirable dose 1 - 5 µm	0.74 mL ± 0.13	0.52 mL ± 0.14

The following particle size specifications were established via performance tests using a seven stage cascade impactor at a flow rate of 15 L/min and 30 L/min equipped with a USP <601> induction port throat. 3 device samples were tested with 3 runs each, for a total of 9 sample points per each drug.

Aerosol was sampled directly from the outlet.

The specifications are listed below with the mean and 95% confidence interval included.

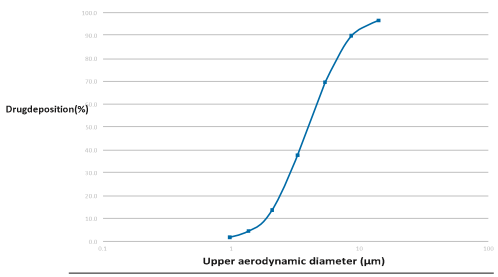
Aerosol specifications

Parameter	Drug	15 L/min extraction flow	30 L/min extraction flow
Mass median aerodynamic diameter (MMAD)	Salbutamol (5 mg/2.5 ml)	3.99 µm ± 0.73	3.90 µm ± 1.04
	Ipratropium bromide (500 µg/2 mL)	3.93 µm ± 0.74	3.87 µm ± 0.90
	Sodium cromoglicate (20 mg/2mL)	4.27 µm ± 0.76	4.02 µm ± 0.91
Geometric standard deviation (GSD)	Salbutamol (5 mg/2.5 ml)	1.82 ± 0.02	2.02 ± 0.11
	Ipratropium bromide (500 µg/2 mL)	1.82 ± 0.03	2.02 ± 0.18
	Sodium cromoglicate (20 mg/2mL)	1.83 ± 0.05	2.00 ± 0.18
Respirable fraction 1 - 5 µm	Salbutamol (5 mg/2.5 ml)	62.7% ± 11.6	56.0% ± 11.9
	Ipratropium bromide (500 µg/2 mL)	63.6% ± 11.8	56.6% ± 9.0
	Sodium cromoglicate (20 mg/2mL)	58.3% ± 11.2	47.9% ± 6.4
Coarse particle fraction >5 µm	Salbutamol (5 mg/2.5 ml)	35.6% ± 12.2	38.9% ± 14.4
	Ipratropium bromide (500 µg/2 mL)	34.7% ± 12.3	38.1% ± 11.4
	Sodium cromoglicate (20 mg/2mL)	40.2% ± 11.6	40.4% ± 11.6
Fine particle fraction <5 µm	Salbutamol (5 mg/2.5 ml)	64.4% ± 12.2	61.1% ± 14.4
	Ipratropium bromide (500 µg/2 mL)	65.3% ± 12.3	61.9% ± 11.4
	Sodium cromoglicate (20 mg/2mL)	59.8% ± 11.6	59.6% ± 11.6
Ultra-fine particle fraction <1 µm	Salbutamol (5 mg/2.5 ml)	1.7% ± 0.6	5.2% ± 2.6
	Ipratropium bromide (500 µg/2 mL)	1.8% ± 0.6	5.4% ± 3.2
	Sodium cromoglicate (20 mg/2mL)	1.5% ± 0.5	11.7% ± 5.8
Respirable dose 1 - 5 µm	Salbutamol (5 mg/2.5 ml)	0.74 mL ± 0.13	0.66 mL ± 0.16
	Ipratropium bromide (500 µg/2 mL)	0.59 mL ± 0.11	0.53 mL ± 0.10
	Sodium cromoglicate (20 mg/2mL)	0.59 mL ± 0.14	0.49 mL ± 0.08
Delivered dose	Salbutamol (5 mg/2.5 ml)	1.19 mL ± 0.06*	
	Ipratropium bromide (500 µg/2 mL)	0.93 mL ± 0.02*	
	Sodium cromoglicate (20 mg/2mL)	1.01 mL ± 0.05*	

* Determined using a simulated breathing pattern (tidal volume = 500 mL, I:E ratio = 1:1, breaths per minute = 15)

Note: Coarse particles (oro-pharyngeal deposition) and ultra-fine particles (exhaled) are not likely to deposit in the patient's airway and thus provide limited clinical benefit.

Cumulative drug deposition – Salbutamol



Performance information provided as required by EN 13544-1:2007 may not apply for medications in suspension or high viscosity form. In such cases information should be sought from the medication supplier.

Performance may vary based on atmospheric pressure depending on altitude above sea level, barometric pressure, and temperature.

Nebulizer performances are based upon testing that utilizes adult ventilatory patterns and are likely to be different from those stated for pediatric (2 years and older) populations.

Electromagnetic information: The InnoSpire Go needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document. Portable and mobile RF communications equipment can affect medical electrical equipment.

The CE mark on the product denotes compliance with all applicable EU Directives. Note that the Notified Body number does not apply to the RoHS (restriction of the use of certain hazardous substances in electrical and electronic equipment) Directive.

Expected service life: N ebulizer handset, battery and mask adapter, 3 years from date of purchase
Mouthpiece assembly, 1 year from date of first use
Masks, 1 year from date of first use

Symbol glossary

Class II internally powered ON device, double insulated

(power)CAUTION

OFF (power)Alternating currentType BF applied parts

Serial numberSeparate

collectionTemperature

limitation

Follow instructions for

useAtmospheric

pressureHumidity

Complies with RTCA/DO-160F category M

ManufacturerDate of

manufacture section 21,

IP22 Ingress Protection rating

Warranty

Respironics, Inc warrants the nebulizer handset and battery to be free from defects in materials and workmanship under normal use and operation for a period of 2 years from date of purchase from Respironics, Inc. The warranty is limited to repair or replacement, at Respironics, Inc's sole option, of any such component or equipment claimed to be defective when claim is shown to be bona fide by evaluation by Respironics, Inc. This warranty does not extend to any components or equipment subjected to misuse, improper operation, accidental damage, or unauthorized repairs, and is not extended to charges of, or for, labor repairs. All items returned must be properly packaged and shipped, prepaid, by the product distributor servicing the unit. Respironics, Inc shall not be liable to purchaser or others for loss of use of equipment or for indirect, or incidental or consequential damages that might arise.