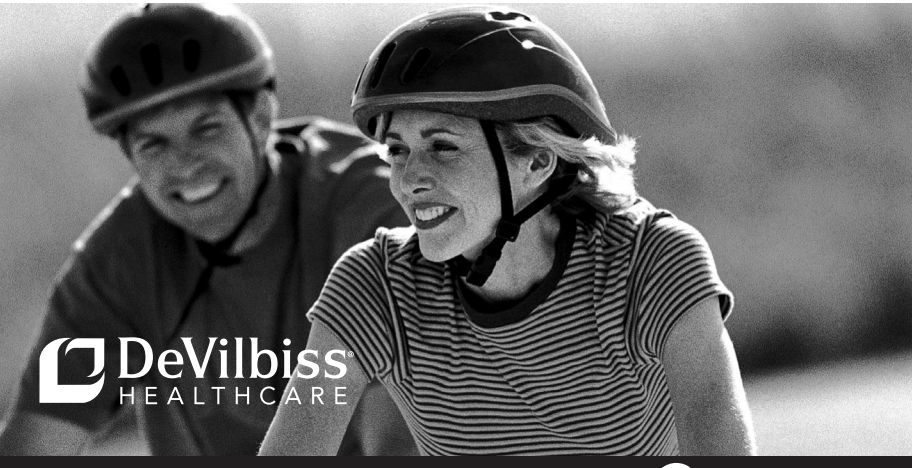


PULSEDOSE® COMPACT CONSERVING DEVICE

C US LR 47089

CE 0044

EN DeVilbiss® PulseDose® Compact Conserving Device

Instruction Guide for Models:
-PD1000I for CGA 870 valve outlet
-PD1000G for German threaded valve outlet

CAUTION–*USA Federal law restricts this device to sale by, or on the order of a physician.*

DANGER– NO SMOKING

ES Aparato de Regulación Compacto PulseDose® DeVilbiss®

Guía Instructiva para los Modelos:
- PD1000I para válvula de descarga CGA 870
- PD1000G para válvula de descarga roscada Alemana

PRECAUCIÓN– *La ley federal de los EE.UU. limita la venta de este aparato a médicso o bajo prescripción facultativa.*

PELIGRO– NO FUMAR

FR Économiseur compact DeVilbiss® PulseDose®

Guide d'instructions des modèles :
- PD1000I pour sortie de robinet CGA 870
- PD1000G pour sortie de robinet fileté, Allemagne

ATTENTION–*La loi fédérale américaine limite la vente de cet appareil par ou sur ordonnance d'un médecin.*

DANGER– INTERDICTION DE FUMER

DE DeVilbiss® PulseDose® Kompakt-Sauerstoff-Einspargerät

Bedienungsanleitung für Modelle:
- PD1000I mit CGA 870 Pin Index Anschluss
- PD1000G mit DIN Anschlusss

ACHTUNG–*Nach US-Bundesgesetzen darf dieses Gerät nur von einem Arzt bzw. auf Anordnung eines Arztes verkauft werden.*

VORSICHT– NICHT RAUCHEN

IT Economizzatore compatto DeVilbiss® PulseDose®

Guida di istruzioni per i modelli:
- PD1000I per scarico valvola CGA 870
- PD1000G per scarico valvola filettato tedesco

ATTENZIONE– *La legge federale statunitense limita la vendita di questo dispositivo ai medici o su loro prescrizione.*

PERICOLO– VIETATO FUMARE

NL DeVilbiss® PulseDose® Compact zuurstofbesparingsapparaat

Instructiehandleiding voor modellen:
- PD1000I voor klepopening CGA 870
- PD1000G voor klepopening met schroefdraad (Duitsland)

ATTENTIE– *De federale wetgeving in de Verenigde Staten schrijft voor dat dit apparaat uitsluitend mag worden verkocht of voorgeschreven door een arts.*

GEVAAR– VERBODEN TE ROKEN

TABLE OF CONTENTS

IEC SYMBOLS

	ATTENTION - Consult Instruction Guide	CE 0044	CE Mark
	DANGER–NO SMOKING	⎓	Direct current, 3VDC
REF	Catalog/Model Number		The device contains electrical and/or electronic equipment that must be recycled per EU Directive 2012/19/EU - Waste Electrical and Electronic Equipment (WEEE)
SN	Serial Number		
	Type BF applied part		

IMPORTANT SAFEGUARDS

The information contained in this guide is intended to assist in the safe operation of the equipment and to ensure maximum benefit is achieved.

This product is to be used only to deliver medical grade (U.S.P.) oxygen and only with a physician's prescription.

READ ALL INSTRUCTIONS BEFORE USING.

SAVE THESE INSTRUCTIONS.

Oxygen supplied by this equipment is not to be considered life-supporting and must not supply anything other than medical grade (U.S.P.) oxygen.

When using electrical products, basic safety precautions should always be followed. Read all instructions before using.

Important information is highlighted by these terms:

DANGER– Urgent safety information for hazards that will cause serious injury or death.
WARNING– Important safety information for hazards that might cause serious injury.
CAUTION– Information for preventing damage to the product.
NOTE– Information to which you should pay special attention.

DANGER

To reduce the risk of fire, burns, or injury to persons:
Oxygen, though non-flammable, vigorously supports and accelerates burning of any flammable material. If you know or suspect oxygen has escaped other than through normal operation, open doors and windows to ventilate the area.

1. DO NOT SMOKE WHILE USING YOUR DEVILBISS OXYGEN EQUIPMENT. Keep matches, cigarettes, burning tobacco, or candles away from the area where the system is being stored or operated.
2. Avoid creation of any spark near oxygen equipment. This includes sparks from static electricity created by any type of friction.
3. Keep the equipment at least seven feet away from radios, television sets, window air conditioners, fans, electric razors, hair dryers, and all other electrical appliances.
4. Keep the equipment away from heat sources, electric or gas heaters of any kind, fireplaces, or stoves.
5. Keep all flammable materials or petroleum-based products away from the equipment.
6. Never attempt to lubricate the equipment.
7. Never use aerosol sprays near the equipment.
8. To avoid strangulation never route oxygen tubing around the neck. Always read and follow the cannula manufacturer's instructions.

To prevent high concentrations of oxygen:

1. Keep the equipment in a well-ventilated area.
2. Do not carry equipment under a coat or any form of clothing.
3. Turn off oxygen supply by closing the cylinder valve when not in use.

WARNING

To reduce the risk of injury:

1. Keep all units away from children. Do not allow unauthorized or untrained individuals to operate the equipment. Never tamper with or try to repair the equipment yourself. If you have any questions or suspect your equipment is not operating properly, contact your oxygen provider.
2. Do not immerse in liquids or subject device to harsh conditions.
3. Do not use in temperatures greater than 104°F (40°C) or below 14°F (-10°C).
4. Do not use with other equipment (i.e. humidifier, nebulizer, etc.) when in PulseDose delivery mode.
5. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

PHYSICIAN'S NOTES

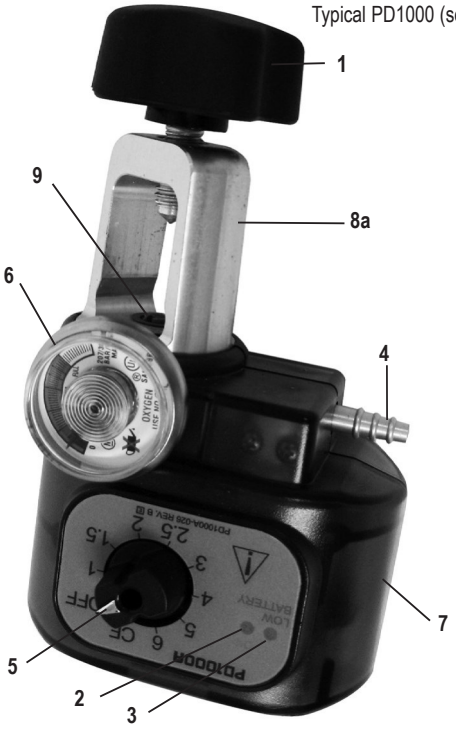
1. Do not use with patients who breathe below 6 Breaths Per Minute (BPM) or above 40 BPM.
2. Do not use with patients who consistently fail to trigger equipment (i.e. mouth breathing with closed soft palates).
3. Verify patient is getting adequate Pa02 or Sa02 levels in PulseDose delivery.
4. Use only standard nasal cannula with PulseDose delivery. Do not use pediatric (low-flow) nasal cannula or mask with PulseDose delivery.
5. A mask or any nasal cannula can be used with continuous flow delivery.
6. The PD1000 series contains an internally controlled preset 2 LPM continuous flow backup. The service manual describes how to change the cannula fitting to obtain a 3, 4, 5 or 6 LPM continuous flow backup.

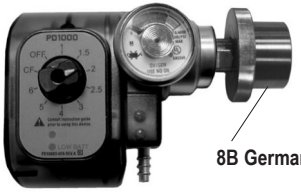
INDICATIONS FOR USE

The DeVilbiss Compact Conserving Device is intended as a delivery device for medical-grade oxygen from high-pressure oxygen cylinders. This is an ambulatory device, which allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder.

IMPORTANT PARTS

Typical PD1000 (series) Front and Rear Product Labeling





1. **Knob**– This knob is used to attach the conserving device to the cylinder. (Model PD1000I only)
2. **PulseDose Indicator**– Either green or red light illuminates each time the unit pulses oxygen.
   Normal Battery Indicator– A flashing green light indicates that there is sufficient battery power.
3. **Low Battery Indicator**– A flashing red light indicates that there are 4 - 8 hours of battery life remaining. The low battery indication time may be reduced when using NiMH batteries.
   Change Battery Indicator– A constant red light indicates that the batteries should be changed immediately. Unit can be used only in continuous flow mode until new batteries are installed.
4. **Cannula Fitting**– Use this fitting to attach the cannula to your PulseDose conserving device.
5. **Rotary Selector**– When this rotary switch is set to "OFF," the unit is not using battery power and will not pulse. When this switch is set to one of the numbers, the unit is on and awaiting inspiration through the nasal cannula at which time it will dose on every breath. The volume of the oxygen delivered varies according to which prescription flow setting is chosen. The final setting on the rotary switch is "CF"; this

is the continuous flow position. In this position oxygen will flow from the cannula fitting at the default continuous flow rate.

6. **Oxygen Contents Gauge**–Indicates the remaining pressure in the oxygen cylinder. When this gauge falls into the red section, you should switch to a new cylinder.
7. **Battery Door**– Use only standard "AA" Alkaline or NiMH batteries. Refer to the instructions supplied with NiMH batteries for use and recharge instructions.
8. **Cylinder Connection**
   8a = CGA 870 Pin Index
   8b = German DIN Threaded Cylinder Connection
9. **Regulator Seal–** Creates a mechanical seal between the tank and the regulator and prevents oxygen leaks.

Alerts

No Inspiration Alert–If the unit is on and inspiration has not been sensed for 15 seconds, the audible and visable alert will pulse until an inhalation is sensed or the selector is turned off.

NOTE–*Continuous flow mode is not powered by the batteries and can be used regardless of the battery level. In the event of a device failure or dead batteries, the user must manually switch the unit to continuous flow for delivery of oxygen. The device will not automatically switch to continuous flow. The oxygen cylinder will not last as long in continuous flow mode as it would in PulseDose mode. Unless there is a problem with the unit, such as dead batteries, the unit should be used in PulseDose mode.*

INTRODUCTION

How PulseDose Works

PulseDose dramatically extends the use time from a supply of oxygen, offering increased mobility with improved comfort and increased efficiency. The reliability and safety of PulseDose oxygen delivery has been proven effective in clinical testing as well as through independent tests performed by physicians and respiratory therapists.

What is PulseDose? The concept is based on the fact that the normal breathing pattern is inhalation for 1/3 of the time, and exhalation about 2/3 of the time. At 20 BPM the oxygen delivered in continuous flow, assuming inspiration is 1/3 of the breathing cycle, would be 16.5 cc/LPM. As a result, PulseDose extends the use time of an oxygen system by an average of 3:1. PulseDose senses the start of inhalation and instantly releases a short "pulsed" dose at the very beginning of the breathing cycle. Since all of the "pulsed" oxygen finds its way deep into the lungs, less oxygen is required to accomplish the same effect than with traditional continuous flow oxygen systems. This means that a PulseDose oxygen system will last two to four times longer than a continuous flow oxygen system, yet still provide the same therapeutic benefit.

Because oxygen is released only during inhalation, the constant flow of oxygen into the nostrils is eliminated. Many users find PulseDose oxygen delivery more comfortable than continuous flow delivery systems. The short "pulse" of oxygen delivered during inhalation is almost undetectable, and the humidity in the room air helps maintain a normal level of moisture in the nasal cavity. This greatly reduces the discomfort of dehydration associated with a continuous flow oxygen system.

Because PulseDose responds to each individual's breathing patterns, the use time will vary for each individual depending on the PulseDose prescription rate and the breath rate. The following chart shows the theoretical ambulatory ranges for DeVilbiss PulseDose products.

NOTE–*All ambulatory ranges are calculated assuming a breath rate of 20 breaths per minute in PulseDose (PD) mode.*

USE TIMES (Shown in Hours)

Delivered Volume cc's	16.5	24.75	33	41.25	49.5	66	82.5	99	
Flow Rate	**1**	**1.5**	**2**	**2.5**	**3**	**4**	**5**	**6**	**Mode**
M6 Cylinder	2.7	1.8	1.4	1.1	.9	.7	.6	.4	**CF**
164 Gaseous Liters	8.3	5.5	4.1	3.3	2.8	2.1	1.7	1.4	**PD**
ML6 Cylinder	2.8	1.9	1.4	1.1	.9	.7	.6	.5	**CF**
170 Gaseous Liters	8.6	5.7	4.3	3.4	2.9	2.1	1.7	1.4	**PD**
C Cylinder	4.0	2.7	2.0	1.6	1.3	1.0	.8	.7	**CF**
240 Gaseous Liters	12.1	8.1	6.1	4.9	4.0	3.0	2.4	2.0	**PD**
D Cylinder	6.9	4.6	3.5	2.8	2.3	1.7	1.4	1.2	**CF**
415 Gaseous Liters	21.0	14.0	10.5	8.4	7.0	5.2	4.2	3.5	**PD**
E Cylinder	11.4	7.6	5.7	4.6	3.8	2.8	2.3	1.9	**CF**
682 Gaseous Liters	34.4	23.0	17.2	13.8	11.5	8.6	6.9	5.8	**PD**

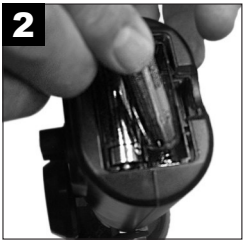
CF=Continuous Flow PD=PulseDose (3 to 1 conserving)

Specifications subject to change without notice. This chart is intended to be used only as a guide. Cylinders vary in gaseous liter capacity by manufacturer which may result in varying use times.

OPERATING INSTRUCTIONS

Inserting A Battery Into The PulseDose Compact Conserving Device

NOTE– *When changing batteries, first turn the rotary selector to the "OFF" position.*



Open the battery door. Insert 2 "AA" Alkaline or NiMH batteries (observe polarity).

Close the battery door.

Attaching Your PulseDose Conserving Device To The Cylinder

Pin Index Connections (Model PD1000I)

Loosen the knob.

Carefully lower the conserving device over the post of the cylinder.

Hand-tighten the knob until the conserving device is secure.

CAUTION– *Alignment pins can damage sealing surfaces of the post increasing the chance of leakage. Align the pins in the conserving device to the alignment holes in the cylinder post.*

NOTE- *Verify that the regulator seal is present and that there are no cuts, tears, or depressions.*

Threaded Cylinder Connections (Model PD1000G)

Align and start the threads on the conserving device with the threads on the oxygen cylinder.

Orient the conserving device so that the control panel is easily viewed and the cannula tubing does not kink.

Hand-tighten the nut until the conserving device is secure.

Using Your PulseDose Compact Conserving Device

Open the cylinder.

Attach the standard nasal cannula to the cannula fitting and to your nose and face. Oxygen tubing up to 35 feet long may be used in PulseDose delivery mode.

Turn “ON” by turning the rotary selector to the prescribed flow setting. Always confirm that the green and red lights flash and you hear the audible alarm beep at startup.

Breathe normally, the conserving device will deliver a bolus of oxygen at the leading edge of inspiration on every breath up to 40 breaths per minute.

When you are finished using oxygen, turn the rotary selector to the “OFF” position. Close the cylinder.

WARNING

To prevent injury from cylinders tipping over, do not use cannula tubing lengths over 10 feet with small compressed oxygen cylinders. Unattended cylinders should be secured in a cylinder stand.

NOTES

- When this rotary selector is set to “OFF,” the unit is not using battery power and will not pulse. When the selector is set to one of the numbers, the unit is on and awaiting inspiration through the nasal cannula at which time it will dose on every breath. The volume of the oxygen delivered varies according to which prescription flow setting is chosen. The final setting on the rotary switch is “CF”; this is the continuous flow position. In this position oxygen will flow from the cannula fitting at the default continuous flow rate.
- Continuous flow mode is not powered by the batteries and can be used regardless of the battery level. In the event of a device failure or dead batteries, the user must manually switch the unit to continuous flow for delivery of oxygen. The device will not automatically switch to continuous flow. The oxygen cylinder will not last as long in continuous flow mode as it would in PulseDose mode. Unless there is a problem with the unit, such as dead batteries, the unit should be used in PulseDose mode.
- When operated within the specified Operating Temperature Range, there is no “warm up” period required. Should the device be outside the specified Operating Temperature Range, allow the unit to stabilize within the Operating Temperature Range prior to use.
- A mask should not be used in the PulseDose delivery mode as it may not fit to the face well enough to allow the conserving device to sense inhalation efforts. Also, the therapeutic effect of PulseDose would not be realized, as the dose of oxygen would be diluted in the mask prior to inhalation.
- A pediatric or low-flow cannula should not be used in PulseDose delivery mode. The reduced diameter of the cannula causes too much back pressure and will affect the oxygen volume delivered.
- PulseDose delivers oxygen in a very short “puff.” It does not deliver oxygen during the entire inhalation. The length of time that PulseDose delivers oxygen will not vary from breath to breath. The time is set in correlation to the oxygen dosage set on the conserving device (patient’s prescription setting).
- PulseDose is designed to prevent the delivery of pulses more than every 1 1/2 seconds. If the breath rate is greater than 40 BPM, this feature prevents delivery of excessive oxygen by not dosing on every breath.
- If using NiMH batteries, carefully monitor when the low battery indicator flashes red. It is recommended that a spare fully-charged set of alkaline batteries be kept in reserve and installed when the change battery indicator is constant red.
- Always follow the Use and Care instructions supplied with the batteries being used. Batteries should be removed when the device will not be used for a week or more.
- The PD1000 series is Latex free. Review the individual material lists for the tubing and cannula used in conjunction with the DeVilbiss products.

TYPICAL QUESTIONS AND ANSWERS

Q. How does PulseDose work? How does it know when I’m inhaling?

A. When inhaling, your diaphragm moves down and causes a drop in pressure in the lungs. Air flows in through the nose and mouth to equalize the pressure. This negative pressure is also present at the nose and mouth during inhalation. This pressure signal travels through the nasal cannula to a pressure sensor in the PulseDose conserving device. An electronic circuit then opens an electrical valve to deliver a precisely metered dose of oxygen. When the valve is closed, the sensor is ready to detect the next inhalation.

Q. The pulse seems so short. Am I really getting enough oxygen?

A. Yes. PulseDose delivers an internally controlled precise burst of oxygen at a relatively high flow rate at the leading edge of each inhalation. This assures that the oxygen delivered flows deep into the lungs for maximum benefit. PulseDose requires less oxygen to deliver the same therapeutic benefit as continuous flow oxygen delivery.

Q. I can’t hear the pulse. Is PulseDose working?

A. If the pulse can’t be heard, simply look at the green PulseDose indicator to see that the device is being triggered by inhalation. For further assurance, hold the end of the cannula in front of your lips while inhaling through your mouth and feel the pulse. PulseDose does not monitor the supply of oxygen.

Remember to check the oxygen contents gauge periodically to verify that there is an adequate oxygen supply. If the oxygen supply runs out, the green PulseDose indicator light will continue to illuminate, indicating that the conserving device is being triggered by inhalation.

Q. Why can't I use a cannula which is longer than 35 feet?

A. The PulseDose triggering is not significantly affected by the cannula length, but the delivery of oxygen is affected. If the cannula is longer than 35 feet, the pulse of oxygen is delayed. Remember the therapeutic moment during the inhalation cycle. If the oxygen is not delivered during this time, the benefits will not be realized.

Q. I've always used humidifiers with oxygen. Should I use a humidifier with PulseDose?

A. No. PulseDose is not able to sense inhalation through the water in the humidifier. Also, many patients find that humidification is not necessary with PulseDose. They find that PulseDose improves comfort because it delivers a very small amount of oxygen during the early part of inhalation, while the rest of the inhalation is composed of normal room air.

Q. When I'm breathing faster, I don't get a pulse with each breath. Don't I need a dose every time?

A. Because PulseDose breathes with the patient, it has an upper limit (40 Breaths Per Minute) that keeps you from getting too much oxygen. When breathing slowly, you receive a dose with every breath. As breath rate increases (up to 40 BPM) PulseDose still delivers a dose with every breath. At this point, you are getting more oxygen per minute because each pulse delivers the same amount of oxygen with each breath while the number of breaths has increased. With continuous flow oxygen, the oxygen delivered is constant. As you breathe faster, the enrichment of inhalations actually decreases because each breath is being diluted with a greater amount of room air.

Q. Why is my conserving device beeping every three seconds?

A. The PulseDose conserving device will beep if breathing is not sensed while the device is on. This could be affected by the cannula position or mouth breathing/shallow breathing.

USER CARE AND MAINTENANCE

The unit should be kept clean and free from moisture and dust. Clean the unit at least weekly by wiping with a dry, lint-free cloth. Avoid getting fluids or debris such as sand or dirt inside the oxygen connections. Do not immerse in water. Do not clean with a solvent based cleaning solution. Avoid dropping the unit or placing it in a position where it could topple or fall since this can damage the device. Whenever possible, use a padded carrying bag such as those listed in the Accessories section to carry the unit. This will help to protect it in case of a fall. The unit should be protected from extreme temperatures. Do not attempt any other maintenance.

STORAGE & HANDLING WARNINGS

When attached to a cylinder, do not place oxygen cylinders in unventilated spaces such as car trunks. Excessive heat can make the relief valve suddenly and quickly discharge the cylinder contents, possibly making it a projectile and greatly increasing the oxygen level in unventilated spaces.

Do not leave oxygen cylinders in the cabs of vehicles without ventilation. If a cylinder leaks, a spark could start a fire causing serious injury or death.

Remove cylinders from the vehicle when the destination is reached. Be sure to secure cylinders from movement during transport.

Heat, Humidity, Sun and Artificial Light have no effect on operation as long as the device is used within the product specifications.

This device contains electrical and/or electronic equipment. Follow local governing ordinances and recycling plans regarding disposal of device components.

TROUBLESHOOTING

WARNING

Do not attempt to open the device for maintenance or repair. The device contains no user-serviceable parts. Do not attempt any other maintenance. Contact your oxygen provider if service is required. If you do not have a healthcare provider, refer to the DeVilbiss contact information on the back of this guide.

SYMPTOMS	POSSIBLE CAUSES	REMEDIES
Oxygen is not being delivered even though the PulseDose indicator is flashing every time I breathe.	1. Oxygen supply is empty.	1. Check contents indicator on the device. If empty, switch cylinders.
	2. Oxygen supply is not turned on.	2. Open the compressed oxygen cylinder valve by following the directions given by your service representative.
Use times are different from those stated in the literature.	1. PulseDose responds to your breath rate. Your breath rate may vary, which causes the operation time to vary.	1. PulseDose is operating correctly.
	2. Leak in system	2. Check connection to cylinder. It may need a new regulator seal.
PulseDose will not pulse	1. Cannula is not attached properly.	1. Check all cannula connections to make sure they are tight, and adjust the cannula to fit comfortably in your nose. Ensure tubing is not kinked.
	2. Unit is not turned on.	2. Turn the rotary selector to the appropriate setting.
	3. Batteries discharged or not installed.	3. Install new batteries.
	4. Mouth breathing with closed soft palates.	4. Breathe through the nose (cannula).
	5. Unit did not reset while changing batteries (red light stays on).	5. Turn the unit off and back on using the rotary selector.
PulseDose works fine for a couple of minutes, then sensitivity seems to drift and may stop working altogether.	1. Using pediatric cannula or any cannula that restricts continuous flow capacity of 10 lpm.	1. Replace with standard nasal cannula.
Green and Red LED's do not illuminate and no "Beep" when the unit is turned "ON".	1. Batteries discharged or not installed.	1. Install new batteries.
	2. Unit defective.	2. Contact your DeVilbiss Provider.
Unit begins to "beep" about 15 seconds after being turned "ON".	1. Cannula is not attached properly.	1. Check all cannula connections to make sure they are tight, and adjust the cannula to fit comfortably in your nose. Ensure tubing is not kinked.
	2. Unit defective.	2. Contact your DeVilbiss Provider.
Red light flashes when breath is detected.	1. Battery charge is low.	1. Replace/recharge (when applicable) batteries.
Red light stays on continuously. Unit will not pulse.	1. Battery charge is depleted.	1. Replace/recharge (when applicable) batteries.

SPECIFICATIONS

Model PD1000I

Weight . . . . . .14.7 ounces; 16.3 ounces with battery

Dimensions. . . . . 4.75"L x 3.4"W x 2.8"H (12.06 cm L x 8.64 cm W x 7.11 cm H)

Model PD1000G

Weight . . . . . .18.9 ounces; 20.5 ounces with battery

Dimensions. . . . . .4.88"L x 3.4"W x 2.8"H (12.4 cm L x 8.64 cm W x 7.11 cm H)

All Models

Power Supply. . . . . (2) Standard "AA" alkaline or NiMH batteries.

Operational Voltage Range . . . . . 2.3 to 3.6V DC

Power Requirements . . . . . Average steady state "ON" current 1.6 uA. Batteries other than alkaline or NiMH are not recommended due to the capacity needed for operation and battery life of the unit. Typical new battery life is 200 hours when used at 25°C, 2 LPM and 20 BPM. Settings and breath rate will affect battery life. After the Low Battery (flashing red) light illuminates, the unit will continue to operate about four hours when used at 25°C, 20 BPM and the 6 LPM setting. Settings, breath rate, and battery conditions will affect use times. Refer to local regulations for battery recycling and/or disposal requirements.

Degree of Protection Against Electric Shock . . . . . .TYPE BF applied part

Modes of Operation . . . . . Continuous / Pulsed

Operating Temperature Range. . . . . .14° to 104°F (-10° to 40°C)

Operating Pressure Range

PD1000I . . . . . .500 to 2250 PSIG (34 to 155 bar—tank pressure)

PD1000G . . . . . .500 to 2901 PSIG (34 to 200 bar—tank pressure)

Operating Atmospheric Conditions. . . . . 500 to 1020 hPa

Operating Humidity Range. . . . . 0 to 95% R. H. non-condensing

Storage and Transportation Temperature Range (Tested at ~933 hPa) . . . . . .-40° to 158°F (-40° to 70°C)

Storage and Transportation Humidity Range (Tested at ~933 hPa) . . . . . 0 to 95% R. H. non-condensing

Expected Shelf and Service Life (excluding batteries) . . . . . .5 years based on 4 hours use per day at 20 BPM

Degree of Protection Against Ingress of Liquids IPX1

Safety Standard . . . . . .meets ISO 18779: 2005(E)

Approval Body And Safety Standard . . . . . Approved by CSA to: IEC 601-1; CAN/CSA-C22.2 No 601.1-M90 as ordinary equipment

US Patents 4,519,387; 5,755,224; 4,457,303

Certified to CAN/CSA C22.2 No. 601.1-M90

CE 0044

ACCESSORIES

The accessories below are approved for use with the DeVilbiss unit:

Carry Bags

- C Cylinder bag EX3000D-651
- D Cylinder bag EX3000D-652
- M6 Cylinder bag EX3000D-653
- ML6 Cylinder bag EX3000D-654

Cylinder cart (E Cylinder) CT001

There are many types of oxygen tubing and cannulas that can be used with this device. Certain accessories may impair the device's performance. Use only standard nasal cannula capable of supporting a minimum flow rate of 10 LPM with PulseDose delivery. Do not use pediatric (low-flow) nasal cannula or mask with PulseDose delivery. A mask or any nasal cannula can be used with continuous flow delivery and may be sized according to your prescription as recommended by your homecare provider who should also give you advice on the proper usage, maintenance, and cleaning.

IMPORTANT INFORMATION

Physician information

Name: _____

Address: _____

_____

Telephone: _____

Emergency Telephone: _____

Prescription Information

Patient's Name: _____

Flow Setting (LPM): _____

Set-up Information

Name of Person Setting Up: _____

Oxygen Provider

Emergency Telephone Number: _____

This instruction guide was reviewed with me and I have been instructed on the safe use and care of the DeVilbiss PulseDose oxygen conserving device.

_____

Patient or Caregiver Signature Date

PROVIDER'S NOTES

No routine calibration or service is required provided the device is used in accordance with the manufacturer's directions. Between patients wipe with a damp cloth having a maximum 5.25% Sodium Hypochlorite (Bleach) or 3% Hydrogen peroxide solution. Avoid getting fluids or debris such as sand or dirt inside the oxygen connections. Do not immerse in water.

DEVILBISS GUIDANCE AND MANUFACTURER'S DECLARATION

WARNING

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the Electromagnetic Compatibility [EMC] information provided in the accompanying documents.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

NOTE– *The EMC tables and other guidelines provide information to the customer or user that is essential in determining the suitability of the Equipment or System for the Electromagnetic Environment of use, and in managing the Electromagnetic Environment of use to permit the Equipment or System to perform its intended use without disturbing other Equipment and Systems or non-medical electrical equipment.*

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions	N/A	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	Complies	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3 V/m. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	N/A	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrical fast transient IEC 61000-4-4	±2kV power line ±1kV I/O lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential ±2kV common	N/A	
Power frequency magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interrupts and voltage variations on power supply input lines IEC 61000-4-11	>95% dip 0.5 cycle 60% dip 5 cycles 70% dip 25 cycles 95% dip 5 secs.	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery.
This device has been tested to and meets the EMC requirements of EN60601-1-2. Do not place the device near other equipment or devices that create or attract electromagnetic fields. Examples of such equipment are defibrillators, diathermy equipment, CB radios, microwave ovens, etc. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit.			