

醫療器材仿單標籤粘貼表

產品中文名稱	“磊士” 氧氣濃縮機	申請廠商	亞靖儀器有限公司
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“磊士” 氧氣濃縮機

製造批號


衛署醫器輸字第 018363 號

製造廠名稱：Respironics, Inc.

製造廠地址：1001 Murry Ridge Lane Murrysville,
PA 15668 USA

藥商名稱：亞靖儀器有限公司

藥商地址：台北縣永和市得和路 269 號 2 樓



96.10.30

- ※ 裝訂原廠之仿單、使用說明書及其中文仿單稿、最小包裝、標籤
- ※ 中文仿單稿包括適應症、禁忌症、型號（規格）、產品說明及注意事項等敘述，最後段須加刊製造廠名稱、地址及藥商名稱、地址，如有附件、配件請一併列明
- ※ 仿單標籤等實物過大或印於玻璃金屬容器等不便於黏貼時可將照相影本代替黏貼報核



“磊士” 氧氣濃縮機

“Respironics” EverFlo Oxygen Concentrator

衛署醫器輸字第 018363 號

使用前請務必詳閱原廠之使用說明書並遵照指示使用

■ 產品敘述

本產品是由一般室內空氣產生濃縮氧氣傳送給需要低流量氧氣治療的病患。這空氣中的氧氣是利用分子過濾器及壓力擺動吸附過程來濃縮。

■ 產品用途

本產品適用於提供補充氧氣給需要氧氣治療的病患。本產品不可做為生命支撐的用途。

■ 警告及注意事項

警告：警告代表有可能對操作人員或病患造成傷害

- 為了適當操作濃縮機要保持良好的通風。這通風口位於機器後面底部而空氣入口過濾器位於側面。保持機器與牆壁、家具至少 15 到 30 公分距離，尤其窗簾會妨礙機器空氣的流通。不可將機器放置於密閉的小空間內。
- 不可拆開機器的蓋子。維修必需委由經原廠授權且訓練過的人員。
- 如果設備警報響起或任何你感到不適的現象須立即請教你的居家照護供應商或健康照護專業人員。
- 經由氧氣濃縮機產生的氧氣是用來增補氧氣，不可做為生命的支撐。氧氣治療可能有風險，在使用本設備前使用者要先瞭解醫療的忠告。
- 當健康照護專業人員因任何理由決定終止這氧氣的供給，對使用者可能有嚴重的後果，必須有交替的氧氣來源能立即的使用。
- 氧氣會激化加速燃燒，必須遠離熱源或火燄。在充滿易燃麻醉氣體或氧氣或笑氣的場所不適宜使用本產品。
- 當使用本產品時不可抽菸，或容許濃煙或火燄靠近機器。
- 不可使用油脂類物質在機器或零組件上，當這類物質與氧氣結合可能增加火災及人員傷害的極大潛在風險。
- 當插座或電源線有損壞時不可使用本產品。不可使用延長線或電子轉接器。
- 當機器插在電源插座時不可清潔本機器。
- 當機器操作時電壓、LPM(每分鐘公升數)、溫度、溼度及海拔高度，超過規格所定數值，會使氧氣濃度降低。
- 居家照護供應商有責任依照原廠的建議定期做預防性保養。

注意事項：注意事項代表有可能對設備造成損壞

- 不可將液體放置或靠近本產品。

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• 若液體濺灑到機器，在清潔前先關閉電源並拔下插頭。若機器無法正常運作時連絡設備供應商。

■ 產品規格：

規格：

輸入電壓	120 伏特交流電 +10 %
輸入頻率	60 赫茲
平均電力消耗	350 瓦
氧氣濃度 (在每分鐘 5 公升)	93 (± 3%)
公升流量	0.5 – 5 每分鐘公升
重量	14 公斤
噪音	45 dBA
尺寸(高 x 寬 x 深)	高 584 mm，寬 381 mm，深 241 mm
氧氣濃度百分比指示警報	低濃度：82%，超低濃度：70%
操作溫度	12 到 32°C
儲存 / 運送溼度	在 -34°C 到 71°C 可達 95 %相對濕度
操作溼度	可達 95 % 相對濕度
出口壓力	5.5 PSI
操作海拔	0 到 2286 m

配件：

壓縮機入口過濾器
微盤過濾器
潮濕器連結管路
流量計固定組
腳輪煞車組

製造廠名稱： Respirationics , Inc.

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藥商名稱：亞靖儀器有限公司

藥商地址：臺北縣永和市得和路 269 號 2 樓

Chapter 1: Introduction

Your health care professional has determined that supplemental oxygen is of benefit to you and has prescribed an oxygen concentrator set at a specific flow setting to meet your needs. DO NOT change the flow settings unless your health care professional tells you to do so. Please read and understand this entire manual before using the device.

Intended Use

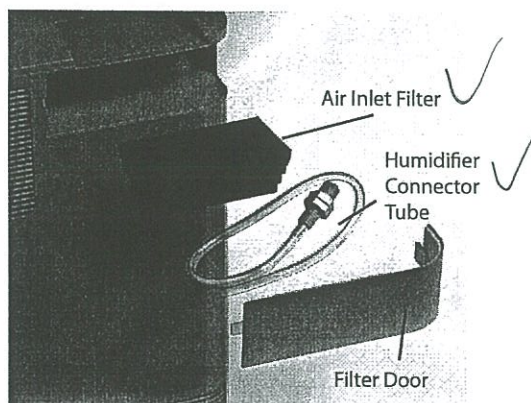
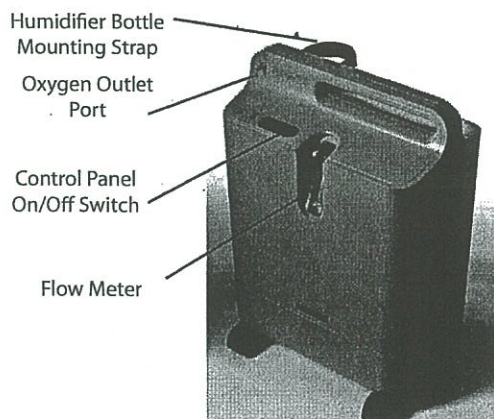
The EverFlo™ Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining.

About Your EverFlo

The device produces concentrated oxygen from room air for delivery to a patient requiring low flow oxygen therapy. The oxygen from the air is concentrated using a molecular sieve and a pressure swing adsorption process. Your home care provider will show you how to operate the concentrator and will be available to answer any questions. If you have additional questions or problems, contact your home care provider.

English

Parts of Your Concentrator



Accessory Equipment and Replacement Parts

Contact your home care provider if you have questions about this equipment. Use only the following Respiroincs accessories and replacement parts with this device:

- Air Inlet Filter
- Humidifier Connector Tube

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Warnings and Cautions

Warnings

A warning represents the possibility of harm to the operator or patient.

- For proper operation, your concentrator requires unobstructed ventilation. The ventilation ports are located at the rear base of the device and at the side air inlet filter. Keep the device at least 6 to 12 inches (15 to 30 cm) away from walls, furniture, and especially curtains that could impede adequate airflow to the device. Do not place the concentrator in a small closed space (such as a closet).
- Do not remove the covers of this device. Servicing must be referred to an authorized and trained Respironics home care provider.
- In the event of an equipment alarm or if you are experiencing any signs of discomfort consult your home care provider and/or your health care professional immediately.
- Oxygen generated by this concentrator is supplemental and should not be considered life supporting or life sustaining. In certain circumstances oxygen therapy can be hazardous; any user should seek medical advice prior to using this device.
- Where the prescribing health care professional has determined that an interruption in the supply of oxygen, for any reason, may have serious consequences to the user, an alternate source of oxygen should be available for immediate use.
- Oxygen vigorously accelerates combustion and should be kept away from heat or open flame. Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Do not smoke, allow others to smoke or have open flames near the concentrator when it is in use.
- Do not use oil or grease on the concentrator or its components as these substances, when combined with oxygen, can greatly increase the potential for a fire hazard and personal injury.
- Do not use the oxygen concentrator if either the plug or power cord is damaged. Do not use extension cords or electrical adapters.
- Do not attempt to clean the concentrator while it is plugged into an electrical outlet.
- Device operation above or outside of the voltage, LPM, temperature, humidity and/or altitude values specified may decrease oxygen concentration levels.
- Your home care provider is responsible for performing appropriate preventive maintenance at the intervals recommended by the device manufacturer.

Cautions

A caution represents the possibility of damage to the equipment.

- Do not place liquids on or near the device.
- If liquid is spilled on the device, turn the power off and unplug from electrical outlet before attempting to clean up spill. Call your home care provider if device does not continue to work properly.

PRODUCT SPECIFICATIONS

Input Voltage	120 VAC +/- 10%
Input Frequency	60Hz
Average Power Consumption	350 Watts
Oxygen Concentration* (at 5 LPM)	93% (+/- 3%)
Liter Flow	0.5-5 liters per minute
Weight	31 lbs (14 kg)
Sound Level	45 dBA typical
Dimensions (HxWxD)	23 in (584 mm) H, 15 in (381 mm) W, 9.5 in (241 mm) D
OPI (Oxygen Percentage Indicator) Alarm Levels	Low Oxygen: 82%, Very Low Oxygen: 70%
Operating Temperature	55°F to 90°F (12°C to 32°C)
Storage/Transport Humidity	-30°F to 160°F (-34°C to 71°C) up to 95% RH
Operating Humidity	Up to 95% relative humidity
Outlet Pressure	5.5 PSI
Operating Altitude	0 to 7,500 ft (0 to 2,286 m)

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EVERFLO™ ORDERING INFORMATION

CONCENTRATOR SYSTEMS	PART NUMBER
EverFlo Oxygen Concentrator	
CONCENTRATOR ACCESSORIES	
Compressor Intake Filter	1038831
Micro Disk Filter	520
Humidifier Connector Tube	1039642
Stand-alone Pediatric Flow Meter	H537-1
Integrated Pediatric Flow Meter	H644
Flow Meter Locking Kit	528
Caster Brake Kit	H649
EverFlo User Manual in English, French, Spanish and Portuguese	1041063
EverFlo Service Manual	1039055
EXTENDED WARRANTY	
Two-Year Extended Warranty with Compressor	1038571

RESPIRONICS

Customer Service: 800-345-6443 or 724-387-4000
 Respiroics Europe, Africa, Middle East: +33-1-47-52-30-00
 Respiroics Asia Pacific: +852-3194-2280
everflo.respiroics.com

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician.

Respiroics is a registered trademark, and EverFlo is a trademark, of Respiroics, Inc. and its affiliates.

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Hoech - WMB 2/14/07 MCI 4100955
 PN 1038667

驗局

RESPIRONICS®



**ALL THE MAKINGS OF A MEGA STAR
WITHOUT THE HIGH MAINTENANCE.**

**PREMIERING THE 31-POUND, LOW-MAINTENANCE EVERFLO™ —
THE OXYGEN CONCENTRATOR THAT COULD GENERATE BLOCKBUSTER SAVINGS.**

800.345.6443

EVERFLO.RESPIRONICS.COM

724.387.4000

THE RESPIRONICS EVERFLO™

EverFlo delivers a great performance and demands so little in return. It's small, quiet and designed to be easier and less expensive to operate. Plus, EverFlo reduces scheduled maintenance visits. So now you can control oxygen therapy costs and deliver all the features you and your patients want with one **31-pound concentrator** that's bound to be the star of your business.

A LOW-MAINTENANCE STAR MAKES YOUR LIFE EASIER.

EverFlo was designed from the ground up to deliver consistent, trouble-free performance and **reduce overall maintenance costs**. A recessed flow meter and a metal cannula connector mean it's less prone to accidental breakage. Since EverFlo is quiet and has an easy-to-use humidifier bottle connection, you may even notice that you're responding to fewer calls from patients. And there are only two filters, which means you can spend less time and money on regular maintenance or repair calls with EverFlo.

SLIM, ATTRACTIVE AND EASY TO WORK WITH.

One of the biggest factors that separate EverFlo from the competition is its size. At just 31 pounds, EverFlo is **small and light** – translating into lower shipping costs, lower storage costs and reduced risk of injury.

A HIT WITH YOUR MOST IMPORTANT AUDIENCE.

Oxygen therapy patients face enough restrictions, which is why we designed the EverFlo to be patient-friendly. It's small, quiet, **uses less electricity and produces less heat**. EverFlo features a compact, non-medical design that fits a patient's surroundings. And with no patient filter and a straightforward humidifier bottle connection, it's simple for patients to use.

MOLDED HANDLE
that's easy to pick up
and transport with
one or both hands

HUMIDIFIER BOTTLE HOLDER
compatible with all bottle styles
and features a Velcro® closure
(on back side of unit)



INTERNAL TUBING STORAGE
keeps tubing conveniently
available for use
(on back side of unit)



METAL CANNULA CONNECTOR
for greater durability



INTERFACE PANEL
with on/off switch and
alarm indicators



RECESSED FLOW METER
reduces the
risk of
breakage





EVERFLO HAS THE FEATURES YOU WANT.

Lightweight and easy to transport – just 31 pounds.

One of the quietest concentrators on the market (45dbA).

No provider filter change for two years.

Available with or without OPI.

5-liter capacity.

EVERFLO DELIVERS THE FEATURES PATIENTS WANT.

Compact, ergonomic design takes up less space, is easier to move.

No patient filter maintenance.

Consumes less power and produces less heat **10.30**

Easy-to-use humidifier bottle connection.

Non-medical design.



**THE RESPIRONICS FREEDOM SERIES™ –
A NEW FAMILY OF PRODUCTS. AND A WHOLE
NEW WAY TO LOOK AT OXYGEN THERAPY.**

The EverFlo Oxygen Concentrator is part of an entire family of products designed to deliver more freedom – freedom from worry, freedom from discomfort and freedom from complicated maintenance. The Respironics Freedom Series frees you and your patients from some of the more arduous aspects of oxygen therapy, so you both can go on with your lives.

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