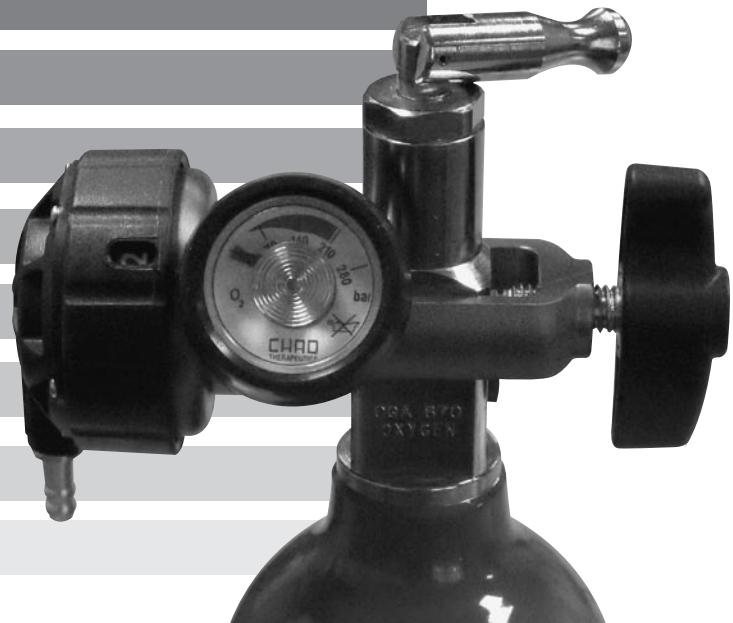
OM-810CE

PRODUCT INFORMATION AND INSTRUCTIONS



CE 0197

CHAD® therapeutics

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GENERAL INFORMATION

This manual provides information necessary to operate the OM-810CE pneumatic conserver with built-in regulator.

This conserver can be used with any CGA 870 post-valve cylinder [see Fig. A] at home or away from home to provide your specific oxygen requirements.

Statements in this manual preceded by the following words are of special significance:

⚠ WARNING!
Indicates there is a possibility of injury to you or others.

CAUTION
Indicates there is a possibility of damage to the device or to other property.

☛ NOTE
Indicates points of particular interest or emphasis that allow for more efficient and convenient operation of the equipment.

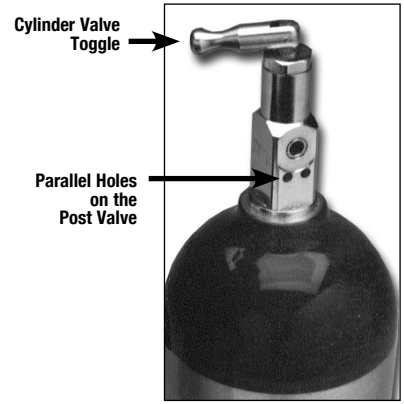

FIGURE A
Post-Valve Cylinder

IMPORTANT SAFETY RULES & PRECAUTIONS

WARNING!

- Read and understand this manual before operating your OM-810CE pneumatic oxygen conserver. Failure to observe the following warnings may result in damage to the unit or injury to life or limb.
- This device is not intended for use during sleep or by patients who:
  - Breathe more than 40 breaths per minute,
  - Consistently fail to trigger equipment (e.g., mouth breathers).
  - This device is not suitable for children.

Smoking near oxygen equipment is strictly prohibited. Keep cigarettes, matches, burning tobacco and open flames, such as lighted candles, away from the area where the system is being stored or operated.

- Avoid creation of any spark, such as static electricity caused by any type of friction, near oxygen equipment.

☛ **NOTE: Oxygen will not burn; however, it does vigorously accelerate the burning of any flammable material.**

- **Keep all parts free of oil and grease.** Hydrocarbon compounds such as oil, grease, petroleum-based products, cleaning agents containing alcohol, hand cream or adhesive bandages can cause explosive reactions if they come into contact with highly compressed oxygen. Please wash and dry your hands properly prior to operating your oxygen equipment.
- **Never** use aerosol sprays near the equipment.
- Do not use in the presence of flammable anesthetic mixture.
- Be sure to turn off the oxygen supply by closing the cylinder valve when not in use.

IMPORTANT SAFETY RULES & PRECAUTIONS

- Do not use cannula tubing that is longer than 7 feet (2.13 m).
- Do not use mask, pediatric, or other low-flow cannula tubing when operating the unit.

CAUTION!

- Your OM-810CE conserver must not be immersed in liquid or cleaned with liquid agents. Prevent water or other liquid substances from entering the unit. Protect your OM-810CE conserver from continued exposure to water, such as rain.
- Protect your OM-810CE conserver from extreme temperatures.
- Please observe the section “Care and Maintenance” on page 15-17 in order to avoid infection or bacterial contamination.
- Prevent dust or any small particles from entering the unit.
- Take care not to get entangled in the nasal cannula tube, which could impede movement and lead to discomfort around the throat.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Always maintain a backup supply of oxygen.
- Do not use humidifier bottles.
- Do not use if leaking or damaged.
- Refer repairs to authorized service personnel.

☛ **NOTE: Oxygen supplied by this equipment is supplemental only and is not intended for life support applications. The OM-810CE conserver should not be used to supply anything other than medical oxygen.**

IMPORTANT SAFETY RULES & PRECAUTIONS

CAUTION! (Cont.)

- Oxygen conserving systems only work reliably upon sufficiently strong inhalation. Therefore, please observe the following:
    - Do not use the OM-810CE conserver at night or while sleeping;
    - Do not use the OM-810CE conserver for babies or children;
    - Do not use the OM-810CE conserver if you only breathe through your mouth.
- Do not use the OM-810CE conserver if you breathe more than 40 breaths per minute
- Closely observe the permissible ambient conditions listed in the “Specifications” section on page 21. Failure to observe them may lead to a fire risk or damage to the unit.
- Tighten all screwed connections by hand only. Do not use a tool.
- Do not use the OM-810CE conserver with a humidifier.
- Do not use if leaking or damaged.
- Always open the cylinder valve slowly.

☛ **NOTE:**

- Always ensure that your oxygen cylinder is sufficiently full. We recommend always keeping a full spare cylinder in reserve.
- **Oxygen supplied by this equipment is supplemental only and is not intended for life support applications. The OM-810CE conserver should not be used to supply anything other than medical oxygen.**

ACCESSORIES/REPAIRS
CAUTION!

- Malfunctions and a lack of biocompatibility may result if third-party articles are used. Please bear in mind that in these cases any guarantee entitlement and liability shall lapse where accessories recommended in the instruction manual or original spare parts are not used.
- Servicing and repair work must only be carried out by the manufacturer (CHAD Therapeutics) or by trained personnel. Refer repairs to authorized personnel.

Please contact your Home Care Provider if you have any questions.

INTRODUCTION

PURPOSE

The OM-810CE pneumatic oxygen conserver includes a combination of a low-pressure regulator and an oxygen conserver. It is designed for use with a cylinder as an ambulatory oxygen system and is capable of delivering a precise amount of supplemental oxygen at the optimal point in the breathing cycle. The conserver greatly increases the efficiency in the delivery of oxygen, maximizing the beneficial effects and eliminating unnecessary oxygen waste.

FUNCTION

When we breathe, approximately one-third of the time is spent inhaling and two-thirds exhaling. As a result, oxygen delivered by continuous flow is wasted during exhalation. By eliminating oxygen flow during exhalation, a two-thirds savings is possible. Additionally, the oxygen available during the very first part of inhalation contributes most to meeting oxygen needs. The OM-810CE conserver takes advantage of these facts to provide maximum efficiency in the delivery of oxygen. This device is designed to be an integral component of a lightweight, long-lasting ambulatory oxygen system.

USER QUALIFICATION

Prior to beginning therapy, patients must be given instruction by qualified personnel in how to operate this unit.

DESCRIPTION OF PARTS & CONTROLS

- **Cylinder Adjustment Knob:** This is used to attach the unit to any CGA 870 post-valve cylinder.
- **Oxygen Pressure Gauge:** Enables the user to monitor the contents of the compressed oxygen cylinder and is protected by a rubber guard. Model OM-810CE is equipped with a gauge that reads up to 4,000 PSI.
- **Selector Switch:** Enables the user to select the desired setting, as well as “OFF” and “cf” (continuous flow). When not in use, the switch should be turned to the “OFF” position.
- **Cylinder Alignment Pins:** When assembling the unit, these parallel pins must be inserted into the holes on the CGA 870 post valve.
- **Seal Washer (Part # 20001720):** Creates the interface between the post valve and the conserver. Besides offering a rugged interface, it also surrounds the oxygen path in a ring of stainless steel or brass.

⚠ **WARNING! Use only a <u>manufacturer-specified seal washer (gasket).</u>**

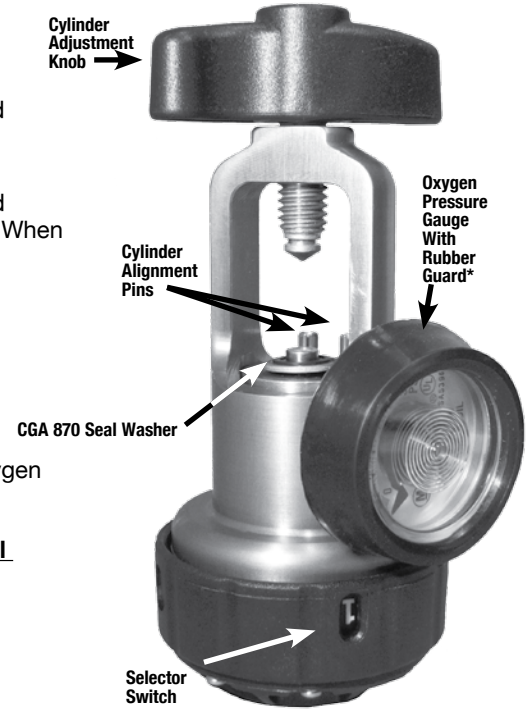

FIGURE B
OM-810CE Conserver

DESCRIPTION OF PARTS & CONTROLS

- **CF Setting:** Enables the user to switch from pulse mode (oxygen delivery on demand) to continuous flow mode in the unlikely event of unit malfunction. The CF setting is designed for emergency use only [see Fig C].

☛ **NOTE: Remember that in continuous flow mode, the oxygen will be consumed at a much faster rate. Return to another source before depleting the oxygen cylinder. The continuous flow function on the conserver is factory preset at 2 lpm.**

- **Oxygen Supply Outlet:** Use this fitting to attach a standard cannula [see Fig D].
- **Vent Hole:** Maintains proper internal pressure. Do not obstruct with any object, such as a label or tight-fitting carrying bag [see Fig D].

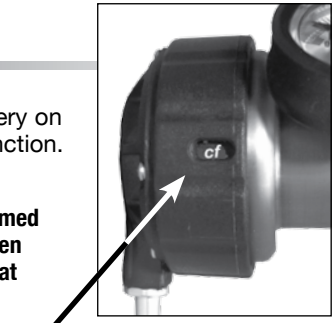

FIGURE C
View of Selector Knob

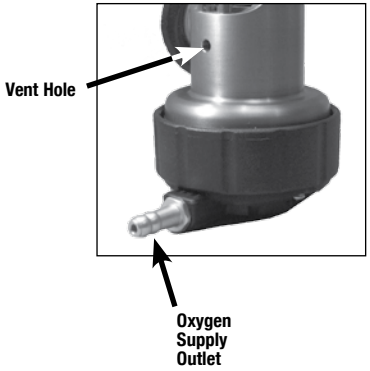

FIGURE D
Back View of the
OM-810CE Conserver

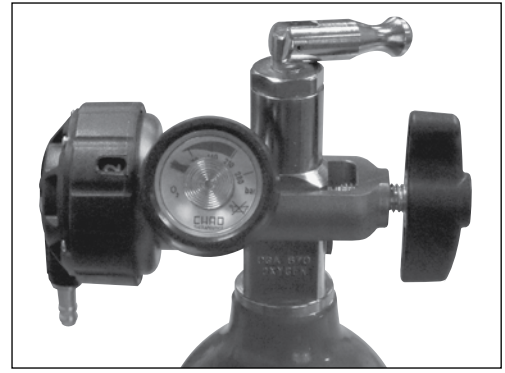

FIGURE E
Connection View of the
OM-810CE Conserver

- Make certain that your hands are free of oil, grease, and other contaminants.
- Inspect the unit to ensure that it has the appropriate seal washer (gasket), in good working condition, attached to the inlet nozzle.
- Secure the cylinder in an upright position.
- Inspect the valve of the cylinder and the conserver to ensure they are free of contaminants. If any indication of damage or contamination is detected, **DO NOT** use the equipment and contact your Home Care Provider.

⚠ **WARNING! Use ONLY a manufacturer-specified seal washer (gasket). An incorrect seal washer (gasket) may not be oxygen compatible or may cause an oxygen leak, creating an increased fire risk. DO NOT use the device if the manufacturer-specified seal washer (gasket) is missing.**

NON-PORTABLE USE:

The OM-810CE conserver is designed to extend the life of portable oxygen supplies when away from the primary source. While the conserver may be used with stationary oxygen sources, the unit should be used only while awake and reasonably attentive. The conserver is not intended for use while asleep because, in the unlikely event of operational malfunction or dislodging of the cannula, the user could be unaware and not make the necessary corrections.

ASSEMBLY AND USE

INSTALLING THE SYSTEM:

STEP 1: Loosen the cylinder adjustment knob.

STEP 2: Lower the OM-810CE conserver over any post-valve cylinder with the alignment pins toward the holes on the cylinder neck [see Fig. F].

STEP 3: Line-up the two pins and the seal washer (gasket) with the corresponding holes on the cylinder post valve.

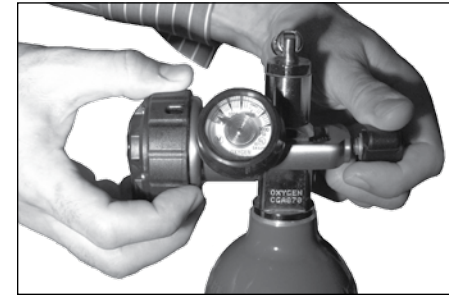

FIGURE F
Attaching the OM-810CE Conserver to the Cylinder

☛ **NOTE: The cylinder adjustment knob should be aligned with the indentation on the post valve.**

STEP 4: While holding the unit in place, tighten the cylinder adjustment knob by turning clockwise [see Fig. F].

☛ **NOTE: Tighten only by hand. The use of a tool to tighten the knob may damage the unit.**

STEP 5: Attach a standard cannula (7 ft. (2.13 m) or less in length) to the oxygen supply outlet.

OPERATING INSTRUCTIONS:

STEP 1: Make sure that the OM-810CE conserver is set to the "OFF" position before opening the cylinder valve.

STEP 2: To reduce the risk of rapid oxygen recompression and fire, open the cylinder valve slowly and completely so the pressure gauge moves slowly as it indicates the cylinder pressure.

STEP 3: Listen for leaks. If a leak is present, close the cylinder valve, check the CGA seal, and reinstall. If the leak persists, **DO NOT USE THE EQUIPMENT**. Contact your Home Care Provider for repair.

STEP 4: Check the oxygen pressure gauge to verify that the cylinder pressure is within the operating range.

STEP 5: Select the setting on the conserver to the appropriate delivery setting [See Fig. G].

STEP 6: As with any nasal cannula, place the nasal cannula into position with the prongs in the nostrils and begin breathing (See Fig. H).

FIGURE G
View of the selector switch

FIGURE H
Proper Positioning of Nasal Cannula

The conserver will now start to deliver oxygen. The amount of oxygen delivered per pulse is determined by the setting. A sound may be heard each time the unit delivers a pulse of oxygen. Adequate saturation will be achieved because of the precise time in the breathing cycle in which the pulse of oxygen is delivered.

☛ **NOTE: To help prevent possible damage to the unit and to maintain its cleanliness, keep the OM-810CE conserver in a carrying bag. Several bags are available for use with different cylinder sizes and configurations.**

STEP 7: When finished using the system, close the oxygen supply cylinder valve and continue breathing through the nasal cannula until no further oxygen is detected and the gauge reads "empty".

STEP 8: Remove the nasal cannula and turn the selector switch to the "OFF" position.

STEP 9: When not in use, store in a clean, dry location.

OXYGEN CYLINDER DURATION

Because the total delivery of oxygen via the OM-810CE conserver is related to breathing rates, it is user adaptive in that the total oxygen delivered per minute will automatically adjust with user need, as expressed by increased or decreased breathing rates. For example, at all settings, twice as much oxygen per minute will be delivered if a person breathes twenty (20) times per minute as compared with ten (10) times per minute. Please refer to the table below as a guide.

OM-810CE	**SETTING**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**cf 2 lpm**
Cylinder Type	Cylinder Volume (Liters)	Estimated Cylinder Duration in Hours (Based on 20 breaths per minute)							
M2	36	2.3	1.4	0.9	0.8	0.7	0.6	0.5	0.3
M4(A)	113	7.2	4.3	2.9	2.4	2.0	1.8	1.6	0.9
M6(B)	164	10.5	6.2	4.3	3.5	3.0	2.6	2.4	1.4
ML6	171	11.0	6.5	4.5	3.7	3.1	2.7	2.5	1.4
M7	198	12.7	7.5	5.2	4.2	3.6	3.2	2.8	1.7
M9(C)	246	15.8	9.3	6.4	5.3	4.5	3.9	3.5	2.1
D	425	27.2	16.1	11.1	9.1	7.7	6.8	6.1	3.5
E	680	43.6	25.8	17.7	14.5	12.3	10.9	9.8	3.7

CARE AND MAINTENANCE

The OM-810CE conserver is designed for a long and accurate life, and does not require maintenance; however, as with any pneumatic device, normal prudent care is required. The unit should be kept clean and free from moisture and dust, as well as extreme temperature. Do not expose the unit to water, such as when bathing or swimming. It is advisable to keep the system in its carrying bag to afford a degree of protection.

Cannula tubing is a disposable accessory that should be replaced periodically following normal usage. Disposable tubing should be disposed of in accordance with local ordinances and/or regulations for disposal. Replacements are available through your Home Care Provider.

HYGIENIC PREPARATION

The unit and its accessories must be hygienically prepared at regular intervals. Also carry out a functional check after the hygienic preparation (see “Assembly and Use” on pages 11-13).

INTERVALS

The unit and its accessories must be cleaned at the intervals listed below. We also recommend carrying out disinfection at these intervals. Please refer to the instructions supplied with the disinfectant used.

CARE AND MAINTENANCE

INTERVAL	COMPONENT	CLEANING	DISINFECTION
As required	Case/Fittings	Wipe down with a lint-free cloth	Wipe disinfection
As required	Carrying Bag	Clean using mild detergent, cold water and a small scrub brush	Wipe disinfection

PROCEDURE

Carry out hygienic preparation of the unit and accessories as described on page 22. We recommend using a 0.5% TERRALIN solution for wipe disinfection. Follow the instructions enclosed with the disinfectant.

WARNING!

- Take special care that no liquids enter the unit, as this may cause damage.
- You should **under no circumstances** use a cleaning agent. Cleaning agents containing alcohol or grease pose a fire risk in combination with compressed oxygen.
- Pay special attention to the oxygen inlet and outlet to make sure they remain free of dust, etc. If the oxygen inlet connection becomes contaminated with dirt, oil, or grease, **DO NOT USE OR ATTEMPT TO CLEAN.** Contact your supplier for service or repair.

CAUTION!

- The carrying bag must never be washed in a washing machine, spin-dried or dried in a laundry dryer.

☛ **NOTE:**

- You are advised to use suitable gloves (e.g. household or disposable gloves) for disinfection work.
- When cleaning your carrying bag, be careful not to scrub the plastic window and do not roughen the seams with the brush. When finished cleaning, rinse with fresh, cold water. Repeat cleaning, if necessary. Hang the bag in a well ventilated area and allow to air dry. Do not hang in direct sunlight, as this may cause its external fabric to fade.

PATIENT CHANGE

Carry out a wipe disinfection on the unit's surfaces before you hand the unit over to a new patient.

PRODUCTS, SPARE PARTS, ACCESSORIES

STANDARD PRODUCT

OM-810CE	CE Certified OM-810CE pneumatic oxygen conserving device with a gauge that reads up to 4,000 PSI

SPARE PARTS

ORDER NUMBER	DESCRIPTION
RP-3040	Black “s” cylinder adjustment knob
20001720	EPDM seal washer (CGA 870)

ACCESSORIES

ORDER NUMBER	DESCRIPTION
OP-150-800	Slimline 3-in-1 carry bag, fits M6, M7 and M9 cylinders
OP-150T	Horizontal carrying tote, fits M4, M6, M7 and M9 cylinders
OC-401S	Adult, single-lumen cannula, 4 ft., case of 50

☛ **NOTE: Only manufacturer-specified seal washers (gaskets) may be used with the OM-810CE conserver. These parts are available from your Home Care Provider.**

PROBLEM	PROBABLE CAUSE	SOLUTION
Unit does not pulse.	Cylinder valve is closed.	Turn the cylinder valve to the "ON" position.
	Cylinder is empty.	Check the oxygen gauge. Replace the cylinder, if empty.
	Oxygen cannula is blocked or kinked.	Remove kinks. Clean or replace, if necessary.
	Selector switch is set to the "OFF" position.	Make sure the selector switch is set to the appropriate delivery setting.
Unit pulses or flows continuously.	Unit is set to the "cf" position.	Turn the selector switch to the appropriate delivery setting.
	Unit was not set to "OFF" prior to opening the cylinder valve.	Turn the selector switch to "OFF," wait a few moments, then set at proper delivery setting.
	Vent hole is obstructed.	Remove obstructions, such as labels or a tight-fitting carrying bag, and resume use as usual.
No oxygen delivery.	Fault in the unit.	Continue the therapy by setting the selector switch to "cf" (continuous flow). This setting increases the oxygen consumption, so you should regularly check how much oxygen you have left.

Non-functioning units are subject to warranty provisions and the manufacturer repair/return policy. If necessary, call your Home Care Provider.

☛ **NOTE: Do not attempt to open the unit. If the unit is opened or tampered with, the warranty is void.**

CLASSIFICATIONS AND SPECIFICATIONS

The OM-810CE conserver is classified as:

- Class II, per FDA 21 CFR Part 868.5905
- Not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Product class according to 93/42/EEC IIa.

SYMBOLS KEY

SYMBOL	MEANING
	Warning, consult accompanying documents
	TYPE PLATE
	Year manufactured
SN	Serial number of the unit
	All the requirements in the applicable EC Directives are fulfilled
	No smoking or open flames
cf	Continuous flow

CLASSIFICATIONS AND SPECIFICATIONS

Oxygen Delivery:

SWITCH POSITION	LITER FLOW EQUIVALENCY (LPM)	ML PER BREATH
OFF	OFF	0
1	1	6-20
2	2	15-29
3	3	25-39
4	4	32-46
5	5	39-53
6	6	45-59
7	7	51-65
cf	2	1.75 - 2.75 lpm continuous

Connection Type: CGA 870
Maximum Breathing Rate: 40 Breaths per Minute
Classification according to EN 60601-1: Degree of protection against harmful ingress of water
Inlet Pressure: Up to 3000 PSI (206 bar)
Continuous Flow Emergency Bypass Setting: Factory preset at 1.75 - 2.75 lpm
Regulator: Brass high-pressure with aluminum low-pressure materials, 25 PSI +/- 5 PSI (1.7 bar +/- .3 bar)
Dimensions: Approximately 5.3" L (13.5 cm) x 2.2" D (5.6 cm)
Weight: Approximately 10 ounces (283 grams)
Operating Temperature: 14˚F to 104˚F (-10˚C to 40˚C)
Operating Relative Humidity: 15% to 95%
Air Pressure Range: 0 to 10,000 feet (0 to 3,048 meters)
Storage/Transportation: Maximum -40°F (-40°C), 1% RH
Maximum 158°F (70°C), 44% RH
Shock: Not to exceed IEC 68-2-27 requirements
Vibration: Not to exceed IEC 68-2-6, IEC 68-2-34

SYMBOLS KEY:  No smoking or open flames.  Warning! Consult accompanying documents.

LIMITED WARRANTY

The OM-810CE oxygen conserver has been carefully manufactured and inspected and is warranted to be free from defects in workmanship and materials. Under this warranty, CHAD Therapeutics' obligation shall be limited to the replacement or repair of any such units or parts that prove, by CHAD's inspection, to be defective within two years from the date of purchase. Any abuse, operation other than the intended use of the product, negligence, accident or repair by other than authorized service professionals shall immediately void this warranty. This warranty does not extend to spare parts or accessories.

CHAD Therapeutics will not accept damages or charges for labor, parts or expenses incurred in making field repairs, except upon written authorization prior to such action.

The foregoing warranty is exclusive and in lieu of all other express warranties. Implied warranties, if any, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, shall not extend beyond the duration of the express warranty provided herein. In no event shall CHAD Therapeutics be liable for loss of use or profit or other collateral, special or consequential damages.

IMPORTANT INFORMATION TO RECORD

Your Name: _____

Date You Received Your Unit: _____

Prescribed Oxygen Flow Setting:

- At Rest: _____
- During Exercise: _____

Home Care Provider's Name: _____

Home Care Provider's Phone Number: (_____)_____

Physician's Name: _____

Physician's Phone Number: (_____)_____

Notes: _____

_____

_____

CHAD®
therapeutics

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