# **C**(¬)**MPASS**HEALTH

# User Manual Compressor Nebulizer

# NEB-SOCCER SOCCER-TRU SOCCER-TRUWB-PB

**CAUTION**–Federal (U.S.A.) law restricts this device to sale by, or on the order of a physician.

Manufactured for Compass Health Brands.

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#### **INTRODUCTION**

The Soccer Ball Nebulizer Compressor System is a medical device designed to deliver medicine prescribed by a physician to the airways of the lungs. The Nebulizer Set and the Air Compressor combined provides aerosol mist for inhalation by the patient for medical treatment only.

#### **Statement of Indication for Use**

The Soccer Ball Nebulizer Compressor is including an AC powered air compressor that provides a source of compressed air for use with a jet nebulizer in a home health care setting. The compressor provides a maximum flow rate of 8 Lpm that can be connected to is used in conjunction with a jet (pneumatic) nebulizer with the same performance specifications to convert certain inhalable drugs into an aerosol form for inhalation by a patient. The patient population is determined by the nebulizer to which it is connected.

The disposable nebulizer cup is used to administer various aerosol treatments to adult and pediatric patients in both the homecare and healthcare settings. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer. The disposable nebulizer cup is disposable, single-patient-use and intended for use with pediatric (5 years and older) and adult patient.

The Reusable Jet Nebulizer is a handheld, pneumatic nebulizer designed to aerosolize prescription drugs for inhalation by a patient. Its use is indicated whenever a healthcare professional administers or prescribes medical aerosol products to a patient using a small volume nebulizer. The Reusable Jet Nebulizer is intended for use with pediatric (2 years and older) and as defined by the prescribed medication and adult patients in hospital/institutional settings, home care use, schools, and long term care facilities.

#### **IEC SYMBOLS**

$\triangle$	Attention - Consult Instruction Guide	<b>†</b>	Type BF equipment– applied part
(li	Consult instructions for use		Double Insulated
$\sim$	Alternating Current	SN	Serial Number
X	This device contains electrical and/or electrical & Electronic Equipmer		It that must be recycled per EU Directive 2012/19/

#### IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, 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.
- **<u>A</u> CAUTION** Information for preventing damage to the product.

**NOTE**– Information to which you should pay special attention.

#### READ ALL INSTRUCTIONS BEFORE USING

### **J** DANGER

#### To reduce the risk of electrocution:

- 1. Always unplug this product immediately after using.
- 2. Do not use while bathing.
- 3. Do not place or store product where it can fall or be pulled into a tub or sink.
- 4. Do not place in or drop into water or other liquid.
- 5. Do not reach for a product that has fallen into water. Unplug immediately.

#### **WARNING**

#### To reduce the risk of burns, electrocution, fire or injury to persons:

- 1. The product should never be left unattended when plugged in.
- 2. Close supervision is necessary when this product is used by, on, or near children or physically incapacitated individuals.
- 3. Use this product only for its intended use as described in this guide. Do not use attachments not recommended by the manufacturer.
- 4. Never operate this product if:
  - a. It has a damaged power cord or plug.
  - b. It is not working properly.
  - c. It has been dropped or damaged.
  - d. It has been dropped into water.

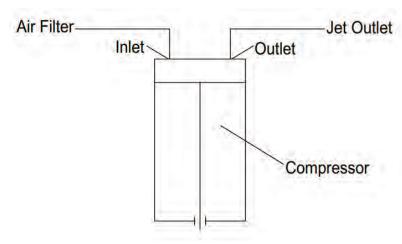
Return the product to an authorized Dealer or Service Provider for examination and repair.

- 5. Keep the power cord away from heated surfaces.
- 6. Never block the air openings of the product or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air openings free of lint, hair, and the like.
- 7. Never use while drowsy or asleep.
- 8. Never drop or insert any object into any opening or hose.
- 9. Do not use outdoors. This product is for household use only.
- 10. Do not use in an oxygen enriched environment.
- 11. Do not operate unit in a backpack or carrying bag.
- 12. Care should be taken when this product is used in the vicinity of other electronic equipment concerning the possible interference between them. They may need to be moved apart.

This is a home use desktop device and it is not intended to be used as a portable device.

#### WORK PRINCIPLE

This unit is compact, simple to operate and convenient to carry It uses a non-oil lubricating, single-cylinder piston pump to create air pressure. The air flow created by the Air Compressor comes out of the jet outlet and then enters the Nebulizer Set. The main air flow into and out of the air compressor unit is illustrated in Figure 1 below.



### **ILLUSTRATION OF PARTS**

NEB-SOCCER Components (Disposable Nebulizer components for Adults and Children 5 Years and Older)

- 1. Mouthpiece
- 2. Medication Cup
- 3. Connection Tubing
- 4. Tube Connector
- 5. Air Openings
- 6. Power Switch
- 7. Filter & Cover
- 8. Resevoir Tube
- 9. T-Adapter
- 10. Aerosol Mask



Figure 1: Disposable Nebulizer

# SOCCER-TRU & SOCCER-TRUWB-PB

Reusable Jet Nebulizer Components

(For Adults and Children

2 Years and Older)

- 1. Mouthpiece
- 2. Cap with Valve
- 3. Nebulizer Insert
- 4. Medicine Cup
- 5. Connection Tubing
- 6. Aerosol Mask

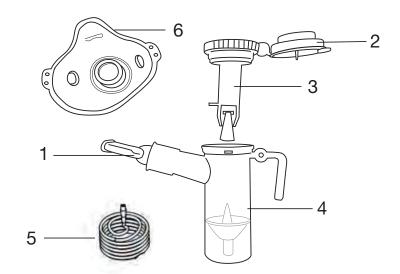


Figure 2: Reusable Jet Nebulizer

#### **GETTING STARTED**

- 1. Check to ensure the following components of the nebulizer are enclosed:
  - Compressor unit
  - Tubing and accessories (see pages 5 for illustration of parts)
- It is recommended to keep extra tubing, accessories and air filters on hand at all times in case original parts become lost, damaged, or soiled.

### **!** CAUTION

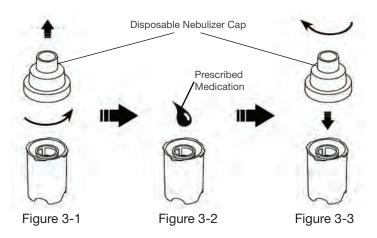
If you did not receive the components listed in this manual, please contact the dealer where you purchased your nebulizer.

#### SETTING UP THE NEBULIZER COMPRESSOR AND NEBULIZER ACCESSORIES

### **!** CAUTION

Tubing and accessories are **NOT** sterile from package. Prior to initial operation, the nebulizer should be thoroughly cleaned.

- 1. Wash hands with soap and warm water and dry completely with a clean towel.
- 2. Place the compressor on a clean, dust-free, stable and flat surface. Check the filter monthly or every 10 12 treatments and replace if dirty, clogged, or wet to ensure proper operation.
- 3. Make sure tubing and accessories have been cleaned and/or disinfected before first use and after last daily treatment. Refer to the Cleaning and Disinfecting Tubing and Accessories section on page 9.
- 4. Remove the nebulizer cap by twisting counter-clockwise until it stops and lift up (Figure 3-1). Be sure that the cone is put inside the bottom section
- 5. Fill nebulizer cup with medication from unit dose vial, eye dropper, or syringe. Do not fill more than 5 ml per treatment (Figure 3-2).
- 6. Close the nebulizer cap and turn clockwise until it is tightened (Figure 3-3).



7. If using the mask (optional), press it directly into the nebulizer cap (Figure 4). If using the mouthpiece, attach it firmly into the nebulizer cap. The cap is designed to fit tightly (Figure 4).

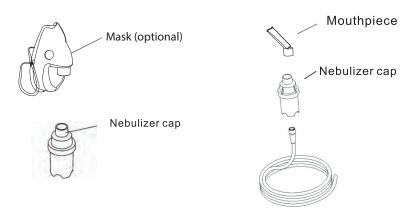


Figure 4

8. If using reusable jet nebulizer reference Figure 5 for instructions.

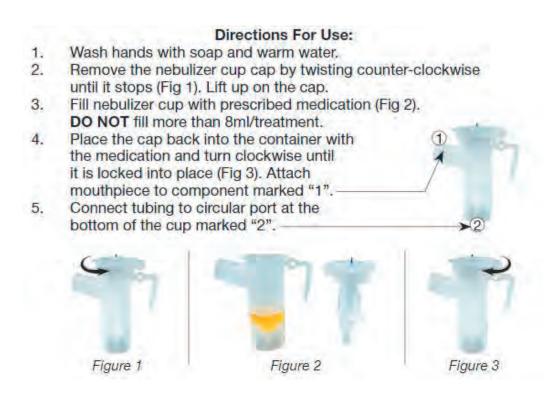
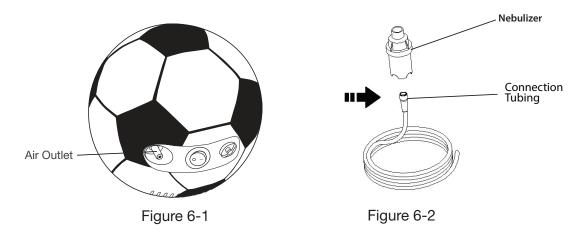


Figure 5

- 9. Attach one end of the tubing firmly onto the air outlet on the back of the compressor unit. It is important that the tubing be pushed all the way onto the air outlet. The tubing is designed to fit tightly (Figure 6-1).
- 10. Firmly press the other end of the tubing onto the bottom of the nebulizer cup (Figure 6-2).



- 11. Plug the power cord into an appropriate electrical outlet. (**DO NOT** use with power strips or extension cords). Make sure at this stage, the power switch is at "OFF" status.
- 12. Press power switch to "ON" status to begin your prescribed treatment. (**DO NOT** run unattended). When treating children, adult supervision required.
- 13. When treatment is finished, shut off the unit and unplug it from the electrical outlet.

#### **WARNING!**

- The exterior surfaces of the unit and the air outlet connector may become slightly warm to the touch during use. Warm air can also be felt exiting the vents on the sides of the case of the unit. This is normal.
- Never operate if this unit has a damaged cord or plug, has been dropped in any way, immersed into water or if it does not work properly. Return it to a service center for repair.
- If any abnormality occurs, discontinue use immediately until the unit has been examined and repaired.
- Always unplug the product immediately after use.
- Never allow the power supply cord to be pulled, jerked, strained, twisted or severely bent, especially at the plug connections. Damage will occur at the high flex point of entry into the appliance, causing it to rupture and short. Handle the cord carefully for longer life.
- Never block the air openings of the main unit or place it where the air openings may be obstructed.
- Safety overload: **DO NOT** exceed 30 minutes of continuous operation.

#### **OPERATION**

To operate the compressor Nebulizer, do the following:

- 1. Plug in the Compressor, but do not connect the Nebulizer Set.
- 2. Make sure that the air filter is attached to the Compressor.
- 3. Turn on the power switch.
- 4. After the Compressor runs properly for 1-2 minutes, connect the jet outlet of the Compressor to the inlet of the Nebulizer Set
- 5. Begin treatment according to your physician's instructions.
- 6. Inhale and exhale naturally. Be sure to stop when the medicine is used up.
- 7. When you have finished, turn the air compressor unit off before you disconnect the air hose.

▲ WARNING - Do not use near flammable objects or locations near explosive materials.

**WARNING** – Nebulizer Set with DISPOSABLE accessory for single patient single use only.

#### COMPRESSOR NEBULIZER CLEANING

- 1. Clean the compressor accessories with distilled water.
- Completely immerse the accessories in 70/30 Isopropyl Alcohol.
- Soak the accessories in the alcohol for approximately 30 minutes.
   Wash and rinse the accessories with warm (approximately 122°F/50°C) distilled water.
- 5. Shake out excess water and dry the accessories with a clean, soft towel or leave the accessories to air-dry.
- 6. Make sure the accessories and other cleaned parts are completely dry and store in a dry, sealed container.

**† DANGER**-Do not submerge in water; doing so will result in compressor damage.

#### FILTER CHANGE

Compass Part No. for Filter is CIF-NEB-5

- 1. Filter should be changed every 6 months or sooner if filter discolors.
- 2. Remove filter by grasping it firmly and pulling out of the unit. Discard old filter.
- 3. Replace with a new filter. Additional filters should be purchased from your Compass provider.
- 4. Push new filter into position.

**CAUTION**-Do not reuse or wash filter or substitute any other material such as cotton for an air-inlet filter. It will result in compressor damage.

#### **MAINTENANCE**

To keep your Compressor Nebulizer working properly, please do follow the instructions in above mentioned cleaning and disinfection processes.

If experiencing a problem regarding the device, such as the device cannot be turned on, noise being too loud, no medicine being dispersed, or water drops forming in the air hose, please proceed to the "TROUBLESHOOTING" guide on the page 12.

**NOTE**–If the problem persists after the above basic maintenance, any further maintenance must be performed by a qualified Compass provider or authorized service center. Please refer to the contact information in the last page of this manual.

**ANGER**-Electric shock hazard. Do not remove compressor cabinet. All disassembly and maintenance must be done by a qualified Compass provider.

#### **SPECIFICATIONS**

Air Compressor Nebulizer Machine Feature	s
Power	120VAC, 60Hz
Electrical outlet	
Power Consumption	200VA
Storage/Transport Temperature Range	-25C to 70C (-13C to 158C)
Storage/Transport Humidity	10 - 95%
Operating Humidity	10 - 95% non-condensing
Operating Temperature Range	10C to 40C (50C to 104C)
Atmospheric Pressure	From 700 hPa – 1060hPa
Max Compressor Flow	8 LPM
Compressor Flow with nebulizer set	5~8 LPM
Max Pressure	30 psi or greater / 206 Kpa or greater
Operating Pressure Range	8~13 psi / 55Kpa~90Kpa
Nebulizer MMAD	5 microns or less
Noise Level	below 63dBA
Dimension (L x W x H)	222 x 173x 100mm
Product Weight	3.2 lbs
Protection against electric shock	Class II
Degree of protection against electric shock	Type BF
Mode of operation	30 min on 30 min off
Recommended shelf life for Nebulizer Set	5 Years
Recommended shelf life for Compressor	2 Years

▲ WARNING: Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

This product complies with the following electromagnetic compatibility standard: IEC 60601-1-2:2nd Edition.

This is a home use desktop device and it is not intended to be used as a portable device.

#### TROUBLESHOOTING GUIDE

Symptom	<b>Probable Cause</b>	Solution
Too much	No filter in the unit	Put a filter in the unit
noise		
The	Main compressor switch is off	Turn the unit on
Nebulizer	Nebulizer was not cleaned after its	Clean the unit
does not	previous use	
run	Air hose is bent	Remove any bend or kink in
		the air hose
	The filter is clogged	Replace the filter
	No medicine is left	Add the appropriate amount of
		medicine prescribed by your
		physician to the Medicine
		Container
	The cap is not attached properly	Reattach the cap
Water	The medicine was over-full	Adjust the amount of medicine
Drops are		in the Medicine Container to
formed in		the appropriate level, connect
the air		the air hose to the Air
hose		Compressor, and turn the unit
		on
	The Nebulizer Kit was washed but	Open and close the Nebulizer
	not dried	Kit repeatedly until the drops
		disappear

**NOTE**-Please contact your COMPASS provider for assistance in case you have any other difficulties.

#### **ELECTROMAGNETIC COMPATIBILITY**

The information contained in this section (such as separation distances) is in general specifically written with regard to Soccer Ball Nebulizer. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

#### **General Notes:**

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use this device.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the equipment is used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

The MODEL will continue to provide air to the nebulizer when exposed to the electromagnetic disturbance levels described below.

## **Electromagnetic Emissions**

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.

Emissions	Compliance	<b>Electromagnetic environment</b>	
	according to		
RF emissions (CISPR 11)	Group 1	The equipment 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.*	
CISPR Emissions Classification	Class B	The equipment is suitable for use in	
Harmonic emissions	Class A	all establishments including domestic	
(IEC 61000-3-2)		establishments and those directly	
Voltage fluctuations / flicker (IEC	Complies	connected to the public low-voltage	
61000-3-3)		power supply network that supplies	
		buildings used for domestic	
		purposes.	

# **Electromagnetic Immunity**

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.

Immunity	IEC 60601-1-2 test	Complianc	Electromagnetic
against	level	e level (of	environment
		this device)	
electrostatic discharge,	contact discharge: ± 6 kV	±8 kV	The relative humidity should be
ESD	air discharge: ± 8 kV	± 15 kV	at least 5 %
(IEC 61000-4-2)			
electrical fast transients	power supply lines: ± 2 kV	± 2 kV	Mains power quality should be
/ bursts	longer input / output lines:		that of a typical commercial,
(IEC 61000-4-4)	± 1 kV	± 1 kV	hospital or home environment.
surges on AC mains	Common mode: ± 2 kV	± 2 kV	Mains power quality should be
lines	differential mode: ± 1 kV	± 1 kV	that of a typical commercial,
(IEC 61000-4-5)			hospital or home environment.

power frequency	3 A/m	30 A/m	Equipment which emits high	
1		3072111		
magnetic field 50/60 Hz			levels of power line magnetic	
(IEC 61000-4-8)			fields (in excess of 30A/m)	
			should be kept at a distance to	
			reduce the likelihood of	
			interference	
			Warning keep Soccer Ball Nebulizer	
			away from sources of high levels	
			of power line magnetic fields	
			(in excess of 30 A/m) to reduce the	
			likelihood of interference.	
voltage dips and short	dip >95%, 0.5 periods	>95%, 0.5	Mains power should be that of a	
interruptions on AC	dip 60%, 5 periods	per.	typical commercial, hospital or	
mains input lines	dip 30%, 25 periods	60%, 5 per.	home environment. If you	
(IEC 61000-4-11)	dip >95%, 5 seconds	30%, 25 per.	requires continued operation	
		>95%, 5 sec.	during power mains interruptions	
			it is recommended that the	
			Soccer Ball Nebulizer	
			be powered from an	
			uninterruptible	
			power supply.ensure	
			power suppry.ensure	

This equipment is intended for use in the electromagnetic environment specified below.  The customer or the user of should assure that it is used in such an environment.				
Immunity test IEC 60601 test level Compliance level Electromagnetic environment – guidance level				

			Portable and mobile RF communications equipment should be used no closer to any part of the, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the
Conducted RF rf coupled into lines	3 V rms 150 kHz to 80 MHz outside ISM bands	3 Vrms	transmitter as below.  Recommended separation distance
(IEC 61000-4-6)	6 VRMS 150 kHz to 80 MHz inside ISM bands	6 Vrms	d=1.2√P
Radiated rf (IEC 61000-4-3)	3 V/m 80 MHz – 2.7 GHz	10 V/m	d=0.58/√P 80 MHz to 800 MHz
			d=0.70√P 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> .
			Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

# Recommended separation distances between portable and mobile RF communications equipment and the equipment

The Soccer Ball Nebulizer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below, according to the maximum

output power of the communications equipment.

Rated maximum output power of	Separation distance according to frequency of transmitters in meters				
transmitter W	150 kHz – 80 MHz 80 MHz to 800MHz 800 MHz to 2.5 GH				
	d=1.2√P	d=1.2√P	d=0.70 <b>√</b> P		
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		
1	1.2	1.2	2.3		
10	3.8	3.8	7.3		
100	12	12	23		

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>&</sup>lt;sup>b</sup> Over the frequency range 150kHz to 80 MHz field strengths should be less than 3 V/m