Coda®

Positive Pressure Unit

User Manual





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Symbols

| ^ | |
|---------------------|---|
| | Caution |
| | Disposal of Device, if you wish to discard electrical and electronic equipment, please contact your dealer or supplier for further information. |
| \sim | Alternating Current |
| ((| Product Certification Authorized by BSI |
| REF | Catalogue Number |
| SN | Serial Number |
| +41°F +5°C | Temperature Limitation |
| 100% | Humidity Limitation |
| 1060 hPa 500 hPa | Atmospheric Pressure Limitation |
| C 253390 US | Canadian Standards Association |
| | Consult Instructions For Use |
| RX Only | By Prescription Only |
| | GS1 DataMatrix Barcode |
| EC REP | Authorized Representative in the European Community |
| | Manufacturer |

General Information

Indication For Use: The Coda Air Purification System may be used as an accessory item during assisted reproductive procedures.

Please familiarize yourself with this manual before using the device.

The Coda® Positive Pressure Unit is a proven technology in IVF and ART to purify the air in your laboratory and improve health conditions for you, your employees, and your family.

Highlights

- The Coda® Positive Pressure Unit is a durable and an effective air purification unit.
- Coda® Positive Pressure Unit filter contains HEPA 99.97%, carbon and potassium permanganate to remove VOCs and CACs.
- The Coda® Positive Pressure Unit filter should be changed at a minimum every 6 months.
- Coda® Positive Pressure Unit has a variable speed fan for your comfort.

Maximize and Support your Central Air Filter System

Most central air heating and air conditioning systems 'dump' larger levels of particulates and VOCs into your space. This is due to inefficient filters and low ratings of filters.

In our study we measured particulate levels of 7000 ppm. By installing a Coda® Positive Pressure Unit you can bring this level to less than 1500 ppm, a significant reduction. The impact is cleaner air and better health. This reduction is important because particulates may carry contaminants onto your samples and into your space.

The Coda® Positive Pressure Unit filter will capture more than 1000 harmful particulates, VOCs, CACs and inorganic compounds.

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LifeGlobal Group, LLC, Guilford, CT 06437 USA

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Catalogue Numbers

| Catalogue #s: | CAPP-115 CAPP-230 |
|--|--|
| Fresh air turnover and air exchanges: Area: 200 sq ft (18.58 sq m) Volume: 1600 cu ft (45.31 cu m) | 18.75 times per hour |
| Fresh air turnover and air exchanges: Area: 600 sq ft (55.74 sq m) Volume: 4800 cu ft (135.9 cu m) | 6.25 times per hour |
| Size of unit dXwXh: in cm | 13.5 x 18 x 73 34 x 46 x 185 |
| Size of Positive Pressure Duct Work | 16.3 m 10.4 m 10 |
| Weight: pounds kilograms | 135 61 |

| 4-stage filter system (4 Canisters | s) | |
|---|---|----------|
| Carbon & Potassium Permanganate Mix | lbs kgs | 24 11 |
| Annual Kit (Install with initial set-up of unit and change 6 months after semi-annual kit.) | N | CPPA-001 |
| Semi-Annual Kit (Change 6 months after annual kit.) | N. C. | CPPS-001 |

Warning & Caution

Warning: To avoid risk of electrical shock, this equipment must only be connected to a supply mains with protected earth.

Avertissement: Pour éviter tout risque de choc électrique, cet appareil doit être branché à une prise de terre avec terre protégée.



CAUTION: Indicates a condition that may lead to equipment damage or malfunction. **ATTENTION:** Indique une condition pouvant entraîner des dommages matériels ou des dysfonctionnements.

Caution: No modification of this equipment is allowed.

Attention: Aucune modification de cet équipement n'est autorisée.

Caution: Do not place the unit in a damp area, in water or under an open window. This may cause damage to the unit.

Attention: Ne pas placer l'appareil dans une zone humide, dans l'eau ou sous une fenêtre ouverte. Cela peut causer des dommages à l'unité.

Caution: Damage to the Coda® Positive Pressure Unit will occur if the unit is put in a damp area, in water or under an open window. Do not operate the Coda® Positive Pressure Unit if it appears to have been dropped or damaged. Federal (U.S.A.) law restricts this device to sale, distribution, or use by or on the order of a licensed medical practitioner.

Attention: Des dommages au Coda[®] Positive Pressure Unit se produiront si l'appareil est mis dans une zone humide, dans l'eau ou sous une fenêtre ouverte. N'utilisez pas le Coda[®] Positive Pressure Unit s'il semble avoir été tombé ou endommagé. Le droit fédéral (États-Unis) restreint la vente, la distribution ou l'utilisation de ce dispositif par un médecin agréé ou sur son ordre.

Servicing the Coda® Positive Pressure Unit

All devices to be returned must be prepared as described below for the protection of the servicing team and for safety during transport. Clean the surface of the Coda® Positive Pressure Unit as described in the "Cleaning the Coda® Positive Pressure Unit" section. Place the unit in the original packaging. Enclose the following information:

Contact Name; Telephone Number; Clinic Address; Description of the fault or service required and proof of purchase.

Ship to:

LifeGlobal Group, LLC, 393 Soundview Rd, Guilford, CT 06437, USA T: 1-800-720-6375 F: 1-519-826-6947 T: 001-519-826-5800 sales@LifeGlobal.com www.LifeGlobalGroup.com

Manufacturing Information

Manufactured By:

LifeGlobal Group, LLC, 393 Soundview Rd, Guilford, CT 06437, USA T: 1-800-720-6375 F: 1-519-826-6947 T: 001-519-826-5800 sales@LifeGlobal.com www.LifeGlobalGroup.com

Authorized Representative:

LifeGlobal Europe, Rue de la Presse 4, 1000, Brussels Belgium T: 32-2 227 1129 F: 32-2 218 3141

Safety Instructions

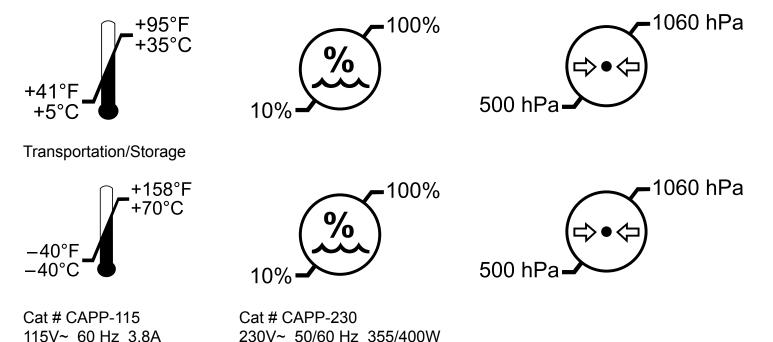
This manual describes the operation and intended use of the Coda® Positive Pressure Unit. It is imperative that you familiarize yourself with the manual before you begin using the Coda® Positive Pressure Unit. Failure to follow these instructions may result in injury to the individual. Incorrect usage of the device may cause the device to break. In the event the device fails, turn off the unit and unplug from the AC outlet immediately.

Other than filter replacement, there are no User Serviceable Parts. Call *Customer Service* for all other issues.

Supply Voltage

The device reflecting catalogue number CAPP-115 operates at a voltage of 115V~ and the device reflecting the catalogue number CAPP-230 operates at a voltage of 230V~. Make sure the power cord is intact and properly grounded.

Operating Environment



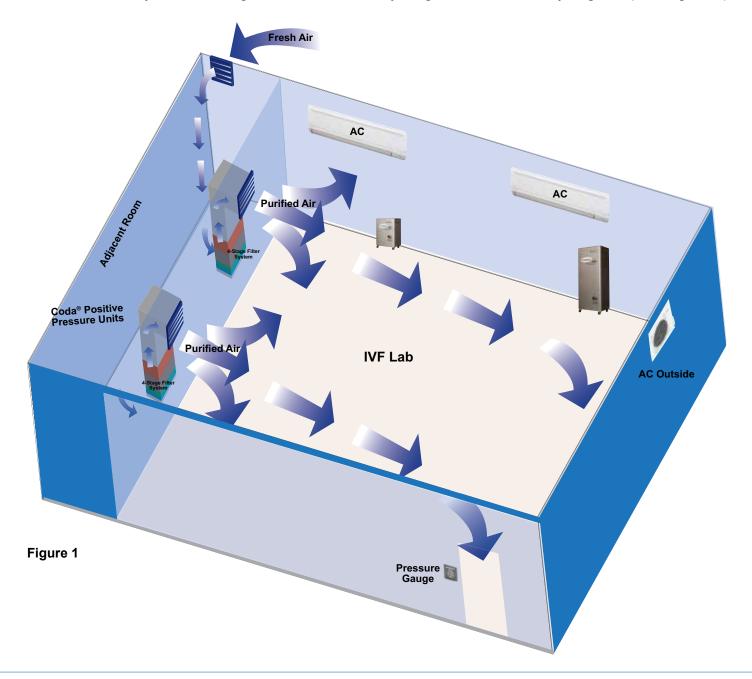
Packaging

The packaging has been designed to maximize safe transportation of the Coda® Positive Pressure Unit and its accessories. After unpacking, keep all packaging for transportation of the device in case of return.

Positioning and Placement of the Coda® Positive Pressure Unit

Rigorous design specifications have been applied in the development of the Coda® System + Positive Pressure Unit to ensure maximum air purification. The Coda® + Positive Pressure Unit reduces the presence of VOCs, bacteria/fungal spores and all particulate matter using a 4-stage filtration system. The design of the unit assures continuous removal of VOCs and particulates in the laboratory.

Our unique design and concept of the Coda® + Positive Pressure Unit reduce VOCs in the air of the IVF laboratory. High quality activated carbon and potassium permanganate act to efficiently absorb all VOCs and aldehydes, reducing their effect on embryos, gametes and embryologists. (see Figure 1)



Installation and Care

Initial Inspection

- 1. Remove the Coda® Positive Pressure Unit from its packaging. Remove the manuals and excess packaging material. Save all packaging material in case of return.
- 2. Check the unit for any damage. Report any damage to *Customer Service* immediately.
- 3. You will need to install a Coda® Positive Pressure Unit Annual Filter Kit.

Installation

Step 1: Secure metal top to the Coda® Positive Pressure Unit using the screws provided. The screw holes have been pre-drilled for easy installation. (see Figure 2)



Figure 2 Figure 3

Step 2: Before doing any measuring or cutting place the Coda[®] Positive Pressure Unit approximately where it is to be installed. Visually make sure it has enough clearance all around the unit and also make sure there is an electrical outlet close by. (see Figure 3)



Step 3: Preparing the wall for cutting the hole required for the positive pressure unit. Measure up from the floor and put a mark at 77.5 inches (196.8 cm). Place the bottom inside edge of the template provided at the mark you just put on the wall. Using painters tape or an appropriate tape secure the template to the wall. Using a pencil trace the inside of the template. This will be your cut mark. Remove the template. (see Figure 4)

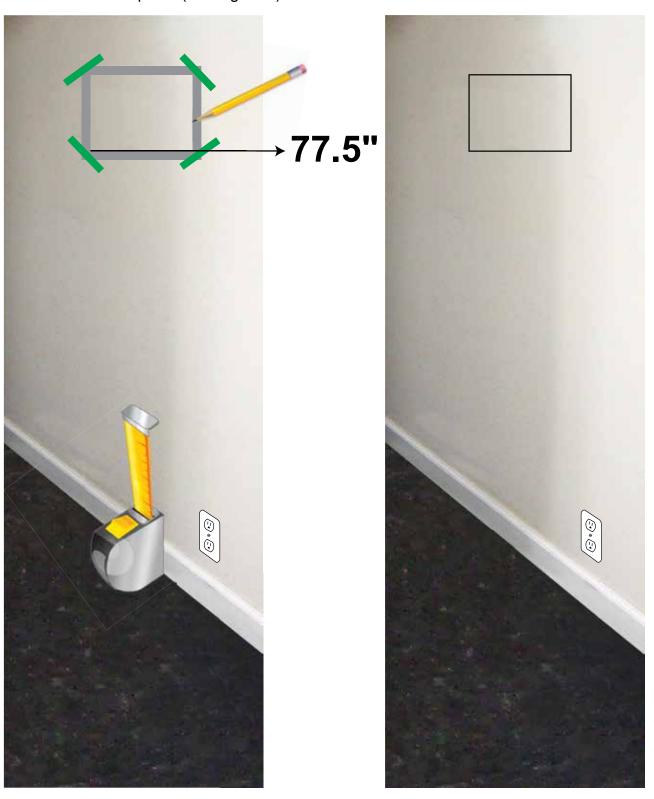


Figure 4

Step 4: Cutting the hole. Using an appropriate saw for the type of wall you have, follow the outline you have drawn and make the cut. (see Figure 5)



Step 5: Place the rubber adhesive gasket onto the metal top where it attaches to the wall. Roll the entire unit up to the hole in the wall. Secure the metal top to the wall using wood screws if using a stud or hollow wall anchors. (see Figure 6)



Figure 5

Figure 6

Step 6: On the inside of the laboratory place rubber adhesive gasket against grill. Then slide the grill into the hole and secure to the wall with wood screws if using a stud or hollow wall anchors. (see Figure 7)



Step 7: Plug the Coda® Positive Pressure into a properly grounded electrical outlet. (see Figure 8)



Figure 7

Figure 8

Filter Replacement

- **1.** Make sure the unit is off. Unplug the power cord.
- 2. Push the top portion of the latch on the side of the Coda® Positive Pressure Unit and pull the bottom of the latch outward. Then turn the latch and release the side panel. Remove the panel. (see Figure 9)
- 3. Carefully remove the appropriate filters and dispose of them in accordance with facility procedures.
- **4.** Dispose of in accordance with procedures in place. Please refer to the section on filter disposal.
- **5.** Carefully place the Coda[®] Positive Pressure Unit filters into the rear of the unit. Make sure it is centered in the opening and upright. (see Figure 10)
- **6.** Replace the side panel and secure the latch.
- **7.** The unit must be plugged into a properly grounded electrical outlet.
- **8.** Store the User Manual in a safe place for future use and for ordering of filters and replacement parts.







Figure 10



CAUTION: Do not place the unit in a damp area, in water or under an open window. This may cause damage to the unit.

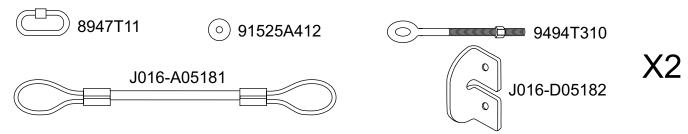
ATTENTION: Ne pas placer l'appareil dans une zone humide, dans l'eau ou sous une fenêtre ouverte. Cela peut causer des dommages à l'unité.

Mounting the Coda® Positive Pressure Unit to the Wall

Note: Mounting the Unit to the Wall is Mandatory
The Use of Brakes on the Castors is Recommended

A mounting kit is included to secure the Coda® Positive Pressure Unit to a wall. The kit provides the necessary hardware to safely secure the unit. Due to the various types of material the wall may be constructed from the user will need to supply proper anchoring devices. Because each instance may present a unique situation these are not included in the kit.

Kit contents:

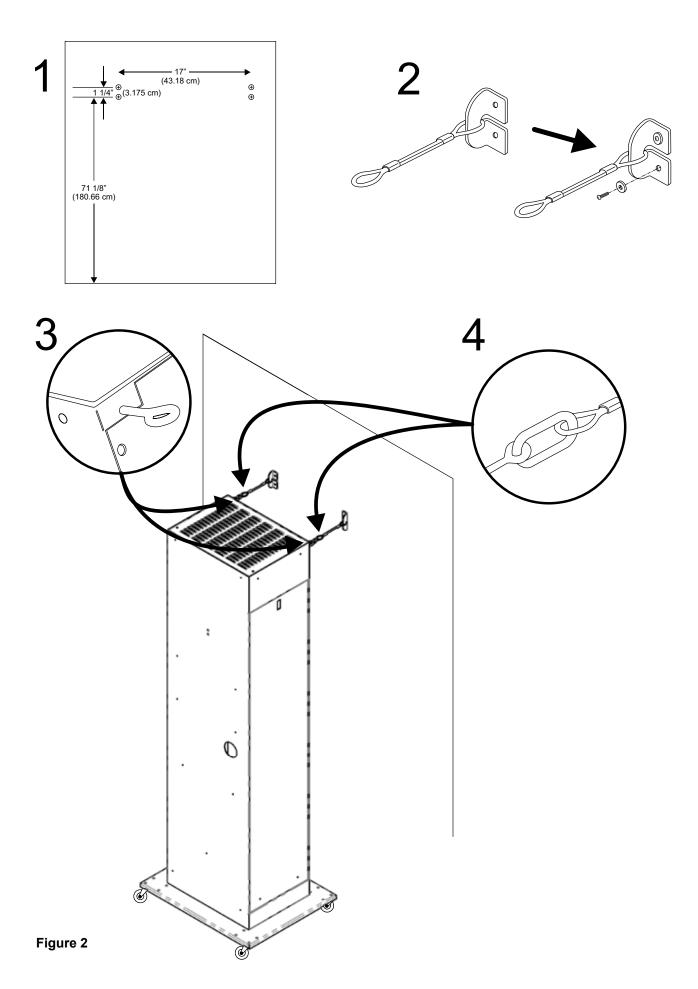


Instructions: (see Figure 2)

- **1.** Drill holes to install wall anchoring device using the dimensions shown. Refer to instructions with the anchoring device for proper hole size and installation.
- 2. Loop the cable end through a bracket slot then secure the wall mount brackets to the wall. Use the oversize washers with the anchoring hardware as shown.
- **3.** Attach the two long close eye bolts to the rear of the Coda® Positive Pressure Unit.
- **4.** Use the oval threaded connector to secure the free end of the cables to the closed eye bolts.

Cleaning the Coda® Positive Pressure Unit

Use a mild house-hold cleaner. Spray the cleaner on a clean soft cloth, then use the cloth to wipe down the unit. Do not spray any liquid directly on the unit.



Warranty

LifeGlobal Group, LLC warrants this product to be free from defects in the workmanship and materials, under normal use and service, for a period of 5 years from the date of purchase. If at any time during this warranty period the product becomes defective or malfunctions LifeGlobal Group, LLC will replace it within a reasonable period of time.

If the product is defective please contact:

- a) the dealer from whom you purchased it, or
- b) LifeGlobal Group, LLC *Customer Service* at 1-800-720-6375, 001-519-826-5800, or email us at customerservice@LifeGlobal.com.
- c) Package the defective product, power supply, and other components as described in our "Servicing the Coda® Positive Pressure Unit" section with proof of purchase and ship it, prepaid to the following address: LifeGlobal Group, LLC, 393 Soundview Road, Department of Returned Goods, Guilford, CT 06437, USA.

This warranty shall not apply if it is shown by LifeGlobal Group, LLC that the defect or malfunction was caused by damage, due to negligence, while the product was in the possession of the consumer.

Only purchase Coda® Positive Pressure Unit filters direct or from a representative to ensure performance and to maintain all your warranties and to know that you are benefiting from the most advanced technology in the market today.

The unit and filters are warranted for a period of one week for shipping and handling damage. If a proper report is not made within this period the damage will not be covered by the company and is now the responsibility of the consumer.

IMPORTANT: LifeGlobal Group, LLC's sole responsibility is to repair or replace the product within the terms of this warranty. LifeGlobal Group, LLC SHALL NOT BE LIABLE FOR ANY LOSS OR DAMAGE OF ANY KIND, INCLUDING ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING, DIRECTLY OR INDIRECTLY, FROM ANY BREACH OF ANY WARRANTY, EXPRESSED OR IMPLIED, OR ANY OTHER FAILURE OF THIS PRODUCT. THE WARRANTIES SET FORTH HEREIN ARE EXCLUSIVE AND LifeGlobal Group, LLC EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, WHETHER WRITTEN, ORAL, IMPLIED OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY, WORKMANSHIP OR FITNESS FOR A PARTICULAR PURPOSE.

If you have any questions concerning this warranty, please contact our *Customer Service* Department at 1-800-720-6375, 001-519-826-5800, e-mail: customerservice@LifeGlobal.com, or write to Customer Service Department at LifeGlobal Group, LLC, 393 Soundview Road, Guilford, CT 06437, USA.

Technical Specifications

Classification (IEC60601-1): Class I

Operating Environment: +41°F to +95°F (+5°C to +35°C), 10-100% relative humidity

(noncondensing), 500 to 1060 hPa

■ Transport/Storage: -40°F to 158°F (-40°C to +70°C), 10-100% relative humidity

(noncondensing), 500 to 1060 hPa

Weight: 135 lbs (61 kg)

Unit Dimensions with Casters: DxWxH 13.5 in x 18 in x 73 in (34 cm x 46 cm x 185 cm)

See Page 4 for Positive Pressure Duct Work dimensions.

Shipping Dimensions: DxWxH 17.5 in x 22 in x 78 in (44 cm x 56 cm x 198 cm)

Power Input: 115V~ 60 Hz 3.8A; 230V~ 50/60 Hz 355/400W

Rated For Continuous Operation

Electromagnetic Emissions: Conforms to the EMC requirements of the Medical Device

Directive 93/42/EEC, CISPR Class A. Tested to EN55011 (2005)

and CISPR11 (2004).

Electromagnetic Immunity: Conforms to the EMC requirements of the Medical Device

Directive 93/42/EEC. Tested to IEC60601-1-2:2004, IEC61000-4-2:2001 ESD, IEC61000-4- 3:2002 RF, IEC61000-4-4:2004 EFT, IEC61000-4-5:2001 Surge, IEC61000-4-6:2001 Conducted RF, IEC61000-4-8:2001 Magnetic Fields, IEC61000-4-11:2004 Voltage Dips, Interruptions and Variations, IEC61000-3-2:2006 Harmonic Distortion, IEC61000-3-3:2005 Voltage Fluctuations

and Flicker.

Electromagnetic Emissions

Guidance and manufacturer's declaration – Electromagnetic emissions The Coda® Positive Pressure Unit is intended for use in the electromagnetic environment specified below. The customer or user of a Coda® Positive Pressure Unit should assure that it is used in such an environment.

| of user of a Coda's Positive Pressure Only should assure that it is used in such an environment. | | | |
|--|----------------|--|--|
| EMISSIONS TEST | COMPLIANCE | ELECTROMAGNETIC ENVIRONMENT – GUIDANCE | |
| RF emissions CISPR 11 | Group 1 | The Coda® Positive Pressure Unit uses RF energy only for its internal functions. 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 | The Coda® Positive Pressure Unit is suitable for use in all establishments including domestic establishments 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 | Not Applicable | | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not Applicable | | |

Electromagnetic Immunity

Guidance and manufacturer's declaration - Electromagnetic emissions

The Coda® Positive Pressure Unit is intended for use in the electromagnetic environment specified below. The customer or user of a Coda® Positive Pressure Unit should assure that it is used in such an environment.

| or user of a Coda® Positive Pressure Unit should assure that it is used in such an environment. | | | |
|---|---|--|--|
| IMMUNITY TEST | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC - GUIDANCE |
| Electrostatic Discharge (ESD) IEC 61000-4-2 | +/- 6kV contact +/- 8kV air | +/- 6kV contact +/- 8kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical Fast Transient/Burst IEC 61000-4-4 | +/- 2kV for power supply lines +/- 1 kV for input/ output lines | +/- 2kV for power supply lines +/- 1 kV for input/ output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | +/- 1kV line(s) to line(s) +/- 2kV line(s) to earth | +/- 1kV line(s) to line(s) +/- 2kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 Cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Coda® Positive Pressure Unit requires continued operation during power interruptions, it is recommended that the unit be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at least characteristic of a typical location in a typical commercial or hospital environment. |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the model DX-4100 or model DX-4102, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Recommended separation distance: $d = \left[\frac{3.5}{V1}\right] \sqrt{P}$ $d = \left[\frac{3.5}{E1}\right] \sqrt{P}$ $d = \left[\frac{7}{E1}\right] \sqrt{P}$ |
| | | | where <i>P</i> 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 meters (m). |

Field strength from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.^b

Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE: UT is the a.c. mains voltage prior to the application of the test level

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.

- ^a Field strengths from 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 Coda® Positive Pressure Unit is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating Coda® Positive Pressure Unit.
- ^b Over the frequency range of 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Coda® Positive Pressure Unit.

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

| Rated maximum output power of transmitter | Separation distance according to the frequency of transmitter | | | |
|---|---|--|--|--|
| (Watts) | (meters) | | | |
| | 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.5 GHz | |
| | $d = \left[\frac{3.5}{V1}\right] \sqrt{P}$ | $d = \left[\frac{3.5}{E1}\right] \sqrt{P}$ | $d = \left[\frac{7}{E1}\right] \sqrt{P}$ | |
| 0.01 | 0.12 | 0.12 | 0.23 | |
| 0.1 | 0.38 | 0.38 | 0.73 | |
| 1 | 1.2 | 1.2 | 23 | |
| 10 | 3.8 | 3.8 | 73 | |
| 100 | 12 | 12 | 23 | |

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meter (m) can be estimated by using the equation applicable to the frequency of the transmitter, where *P* is the maximum 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 many not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures objects and people.

Troubleshooting

Q. Why is my Coda® Positive Pressure Unit not working?

- A. Make sure the power cord is connected properly. If it is still not working, try using another standard power cord.
 - Make sure the power is ON.

Q. Why is my Coda® Positive Pressure Unit making unusual sounds?

A. – Make sure the filter is installed and sitting in the correct position.

If there are no problems with any of the above, please contact LifeGlobal Group, LLC for warranty service.

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