



Cadence™ Self-Breathing System

Quick Reference Card

Introduction

Cadence Self-Breathing System is indicated for the treatment of hypoxemia with delivery of transtracheal high flows of a heated and humidified air/oxygen mixture to self-breathing patients with a cuff deflated fenestrated tracheostomy tube. Cadence Self-Breathing Therapy is intended for adults greater than or equal to 160cm (63 inches) tall and a body mass greater than or equal to 30kg (66 pounds).

Configuration of the Cadence Self-Breathing System allows for the controlled delivery of flow, oxygen concentration, heat, and humidity. It also offers additional safety features.

Please read these instructions, the Cadence™ Self-Breathing System Operator's Manual (p/n 1025632) and all manufacturer component operator manuals before using the Cadence Self-Breathing System on a patient.

The Cadence Gas Delivery System is intended for use only with the Cadence Catheter and Mid-section Hose.

The Cadence Self-Breathing System should only be used with the following cuffed fenestrated tracheostomy tubes:

- Portex Blue Line (sizes 7, 8, & 9 mm)
- Shiley DFEN (sizes 6 & 8 mm)
- Boston Medical Tracoe Twist (sizes 6, 7, 8, & 9 mm)
- Portex D.I.C. (sizes 6, 7, 8, & 9 mm)
- Portex Ultra (sizes 6, 7, 8, & 9 mm)

These tracheostomy tubes will be referenced throughout this document as "Qualified Tracheostomy Tubes".

Two of the Qualified Tracheostomy Tubes, Boston Medical Tracoe, and Shiley, employ separate fenestrated inner cannulas with the 15 mm connector integrated into the inner cannulas. The fenestrated inner cannula, when in place, has fenestrations that line up with the fenestrations on the tracheostomy tube shaft. The Portex DIC, Ultra, and Blue Line do not require separate inner cannulas for the fenestrations to be open with a 15 mm connection available. Removal of the

non-fenestrated inner cannula on these Qualified Tracheostomy Tubes is required for use with the Cadence System.

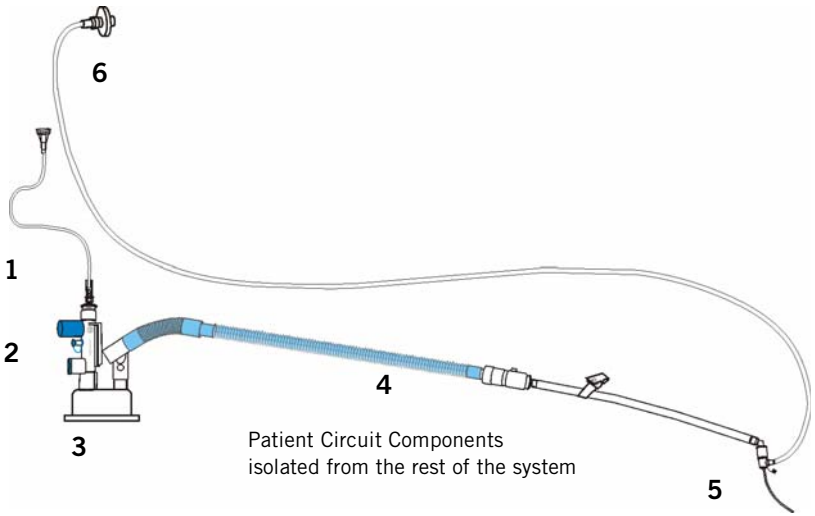


Figure 1: Cadence Patient Circuit Components

Patient Circuit Components

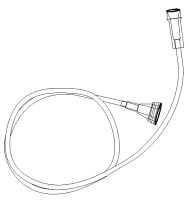
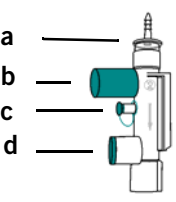
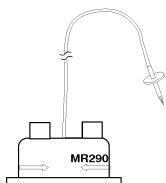
Patient Circuit Components	
1	 <p>Oxygen tubing (1) with built in flowmeter connector (2 foot) (included in patient circuit kit P/N 1028232)</p>
2	 <p>40 cm H₂O Pressure Relief Valve Manifold with Barbed Nipple Adaptor (15 mm)(1) a. barbed nipple adaptor (inlet port) b. pressure relief valve c. pressure monitor port d. oxygen monitor port (included in patient circuit kit P/N 1028232)</p>

Table 1: Cadence Patient Circuit Components (Sheet 1 of 2)

Patient Circuit Components

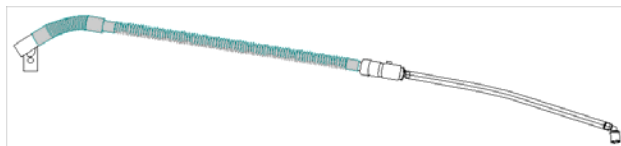
3



MR290 Humidification Chamber (1) with autofeed line

Additional MR290 chamber should be obtained from a local supplier.

4



Heated Wire Patient Circuit (15mm x 6 foot) and Cadence Mid-section Hose (15 inches) (1) (included in patient circuit kit P/N 1028232)

5



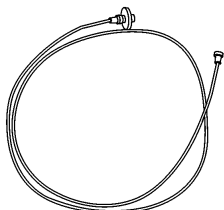
Cadence Transtracheal Catheter (size 11.5, 13.5 or 15.5 cm) (1)

11.5 cm P/N 1025010

13.5 cm P/N 1024999

15.5 cm P/N 1024960

6



Airway Pressure Monitor Line and filter (1)

(included in patient circuit kit P/N 1028232)

Not included with the Cadence Self-Breathing System.

- Portex Blue Line Fenestrated Tube (Size 7, 8 or 9 mm).
7mm, Portex Fenestrated Tube P/N 1025037
8mm, Portex Fenestrated Tube P/N 1025014
9mm, Portex Fenestrated Tube P/N 1025011
- Shiley DFEN (Size 6 & 8 mm)
- Boston medical Tracoe Twist (Sizes 6, 7, 8, & 9 mm)
- Portex D.I.C. (Sizes 6, 7, 8, & 9 mm)
- Portex Ultra (Sizes 6, 7, 8, & 9 mm)
- Use ONLY Qualified Tracheostomy Tubes with the Cadence Self-Breathing System
- Medical Grade Sterile Water Bag

Table 1: Cadence Patient Circuit Components (Sheet 2 of 2)

Assembly Instructions

1. Locate an MR290 humidification chamber and pressure relief valve manifold. Attach the pressure relief manifold on the inlet side of the chamber. Slide the chamber onto the humidifier base. The arrow indicating flow direction should be pointed at the humidification chamber.

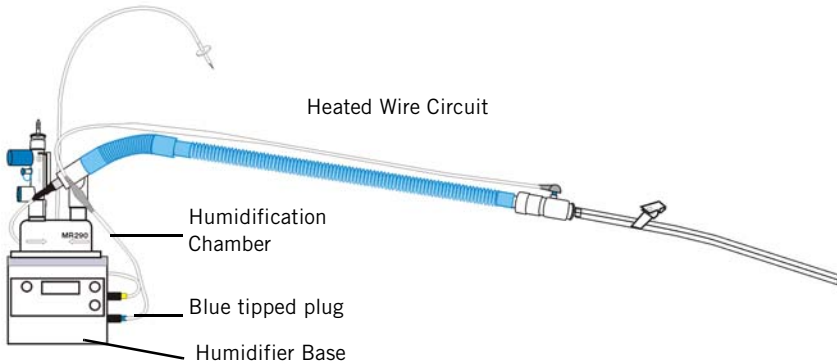


Figure 2: Humidifier with heated wire circuit

2. Locate the temperature probe and push the blue tipped plug into the blue receptacle on the humidifier base until an audible click is heard.
3. Locate the disposable heated wire circuit and connect the 22 mm 'wye' portion of the circuit to the unused outlet of the humidifier chamber. Note that either inlet on the humidifier chamber may be used; however for easy use, connect the heated wire circuit to the chamber outlet closest to the patient.
4. Push the blue chamber probe and airway probes into the heated wire circuit. Make sure the chamber probe is correctly located with the 'V's matching. Also make sure that both probes are fully inserted.

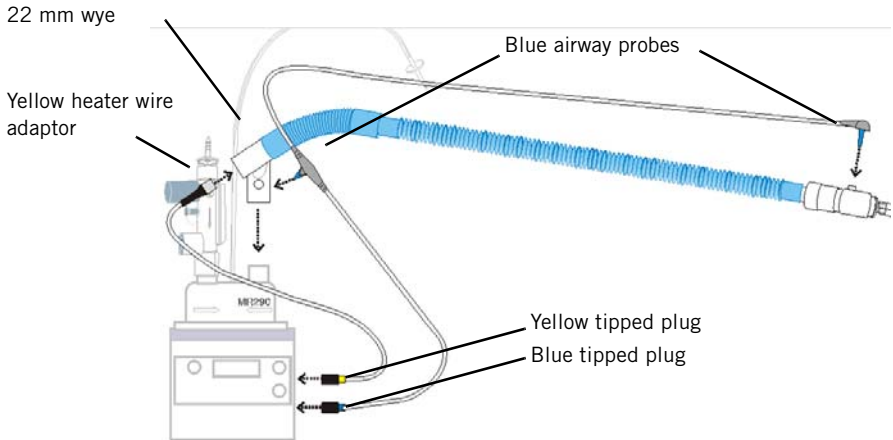


Figure 3: Humidifier and heated wire circuit connections

5. Locate the yellow heater wire adaptor and push the yellow tipped plug into the humidifier controller base. Push the other end of the adaptor into the plug on the end of the breathing circuit. The heated wire circuit is now connected to the humidifier.
6. Connect the Cadence Mid-section Hose to open end of the circuit if not already attached.
7. Hang the free end of the heated wire patient circuit with attached mid-section hose over one of the hooks of the medical stand to ensure that it does not become contaminated by falling on the floor or coming into contact with contaminated equipment.
8. Locate the oxygen tubing (B in Figure 4) with the built-in threaded flowmeter connector (A in Figure 4). Connect the female threaded end of the oxygen tubing onto the outlet of the flowmeter.
9. Connect the other end of the oxygen tubing to the pressure relief valve via the barbed portion of the 15 mm barbed adaptor (C in Figure 4).

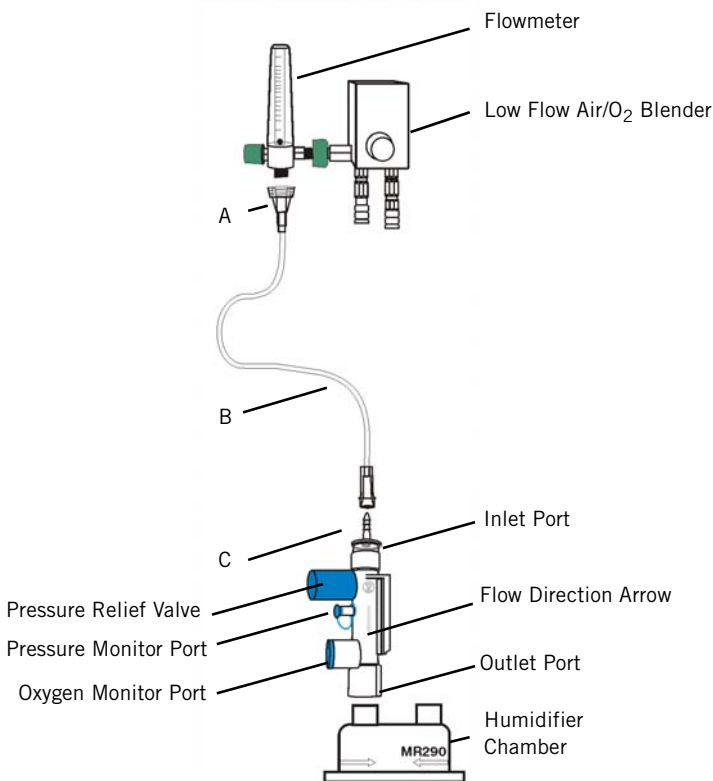


Figure 4: Flowmeter, Pressure Relief Valve and Humidifier Chamber connections

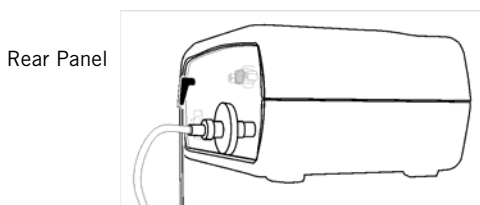


Figure 5: Pressure Monitor Line Connection to Airway Pressure Monitor

10. Finally, connect the airway pressure monitor line to the rear of the Criterion 40 Airway Pressure Monitor (Figure 5). Hang the line over the accessory arm to ensure that it does not become contaminated by falling on the floor or coming into contact with contaminated equipment.
11. At this point, the Cadence Gas Delivery System with the disposable components, except for the Cadence Catheter should be in place but the humidifier and flowmeter should not be turned on.
12. Run a Pre-Operational Test as described in chapter 6 of the Cadence Self-Breathing System Operator's Manual.

Settings

The self-breathing trial may be initiated provided that the patient has been properly prepared using the Deflated Cuff Occlusion Procedure (See “Deflated Cuff Occlusion Procedure”, Chapter 3 of the Operator’s Manual). Once the Cadence Self-Breathing Gas Delivery System and circuit are completely assembled and operational at the bedside and the appropriate Cadence Transtracheal Catheter and related supplies are available then the initial settings may be applied. Monitoring should be in place and qualified clinicians available to assess the patient during the Trial.

Cadence Self-Breathing System Initial Settings	
Component Function	Value
Air pressure (if wall air is not available)	50 PSI
Flow Rate	6-15 L/min but generally between 10 and 12 L/min
O ₂ Concentration	Physician prescribed FiO ₂ (adjustable from 21-77%)
Humidification	Temperature automatically set when in invasive mode

Table 2: Cadence Self-Breathing System Initial Settings

Warnings and Cautions

Please consult the Cadence Self-Breathing System Operator’s Manual for a comprehensive list of Warnings and Cautions.

Warnings

- Universal precautions should be employed when using the Cadence Self-Breathing System.
- Read this entire manual and all manufacturer component operator manuals before using the Cadence Self-Breathing System on a patient.
- Patients using the system should be monitored by trained medical personnel.
- Do not use Cadence Self-Breathing System simultaneously with mechanical ventilation.
- The Cadence Self-Breathing System is for conducting self-breathing trials in patients with tracheostomies. It is NOT intended for use in patients with endotracheal tubes.
- Do not add, subtract or substitute other parts of the Cadence Self-Breathing System. Use only those parts supplied or recommended by Respirationics unless otherwise directed. Failure to do so could reduce or eliminate the patient safety and efficacy mechanisms included in the design.

- Use only Qualified Tracheostomy tubes.
- Use a pulse oximeter with alarm when using the Cadence Self-Breathing System on a patient.
- Do not use when tracheostomy tube decannulation of the patient has occurred.
- Verify that all applicable filters and water traps are in place prior to using the Cadence System. See “Filters & Water Traps” in Chapter 4 of the Operator’s Manual.
- Always monitor that the gas supply pressures are within 50 +/- 10 psig
- To reduce the risk of oxygen toxicity do not exceed 77% oxygen.
- Use only medical grade dry air and oxygen at a supply pressure measuring between 40 - 60 psi. Do not allow supply pressures for either air or oxygen greater than 60 psi or less than 40 psi
- The airway pressure monitor, humidifier and optional compressor must be plugged into a dedicated, properly grounded, hospital grade outlet (120V, 60Hz, >15A). Do not use an outlet that is controlled by a wall switch.
- Use only the Fisher & Paykel MR850 Humidification System with MR290 humidification chambers and the Cadence™ Patient Circuit P/N 1028232.
- Operate the Fisher & Paykel MR850 Humidifier in Invasive Mode only.
- Watch for excessive condensate in the heated wire circuit. Excessive condensate in the heated wire circuit could cause aspiration. Clinician must disconnect circuit and drain it if condensation becomes excessive.
- The Cadence Transtracheal Catheter is intended to be for Single Use Only.
- Refer to manufacturer’s instructions and follow institutional infection control guidelines when disposing of patient used plastic products. This is medical waste, DO NOT recycle.

Cautions

- Federal law (U.S.A.) restricts this device to sale by or on order of a licensed physician.
- If using the external Easy Air compressor unit, do not operate the Cadence Self-Breathing System or the external compressor without having the cooling coil and condensation trap in place.
- Monitor/measure the oxygen content of the gas stream and compare it with the blender setting. If there is significant mismatch, have the blender serviced.
- Reposition the Cadence mid-section hose and the heated wire circuit prior to taking a chest radiograph (x-ray) so that the heated wire circuit does not obscure the view of the chest cavity.

Patient Selection Checklist

Patient Selection Checklist	
Criteria Met	Patient Criteria
	The patient is an adult.
	The patient is greater than or equal to 160 cm (63 inches) tall.
	The patient has a body mass greater than or equal to 30 kg (66 pounds).
	The patient is free of surgical complications, fever, infection, inflammation and hemodynamic instability.
	The patient is able to move air readily in and out past the tracheostomy tube with the cuff deflated and the tracheostomy tube occluded.
	The patient has a Qualified Tracheostomy tube.
	The patient can adequately communicate with the care team.
	The patient has NOT had a recent tracheotomy or tracheotomy revision with post procedure inflammation, edema, and/or bleeding.
	The patient does NOT have airway abnormalities that impair proper functioning of the tracheostomy tube.
	The patient does NOT have a tracheostomy tube oversized for patient's trachea.
	The patient does NOT need an inflated tracheostomy tube cuff.
	The patient does NOT use a foam filled cuffed tracheostomy tube.
	The patient does NOT have significantly impaired swallow or significant aspiration of gastric content.
	The patient does NOT have copious uncontrolled upper airway secretions.
	The patient does NOT have significant problems with mucus plugging.
	The patient does NOT have a lack of medical readiness for self-breathing trial.
	The patient does NOT have high PEEP requirements.
	The patient does NOT have high FiO ₂ requirements.
	The patient does NOT have a severely impaired ventilatory drive.
	The patient does NOT have respiratory muscle fatigue or paralysis.
	The patient does NOT have unresolved disease acute phase process (infection, sepsis, bleeding).
	The patient does NOT have an unstable post surgical condition.
	The patient does NOT have hemodynamic instability.
	The patient does NOT have fever.
	The patient does NOT have significant respiratory acidosis.
	The patient does NOT have unstable metabolic status.

Table 1-1: Patient Selection Checklist (Sheet 1 of 2)

Patient Selection Checklist (Continued)

- The patient does NOT have anemia.
- The patient does NOT have absence of cough reflex.
- The patient is NOT unconsciousness or experiencing delirium.
- The patient does NOT have severe agitation and/or significant sedation requirements.

Table 1-1: Patient Selection Checklist (Sheet 2 of 2)

Catheter Selection

Table 3: estimates the distance that the selected catheter tip for any given model will extend beyond the tip of the Qualified Tracheostomy Tube that was in place when the chest radiograph (x-ray) was obtained:

Estimation of initial catheter size based on chest radiograph (Distance from carina is measured below in centimeters)			
Tracheostomy Tube	11.5 cm	13.5 cm	15.5 cm
Portex BL 7	2 cm	4 cm	6 cm
Portex BL 8	1 cm	3 cm	5 cm
Portex BL 9	0 cm	2 cm	4 cm
Shiley 6	0.3 cm	2.3 cm	4.4 cm
Shiley 8	0 cm	2 cm	4.0 cm
Portex DIC 6	1.3 cm	3.2 cm	5.3 cm
Portex DIC 7	0.6 cm	2.6 cm	4.8 cm
Portex DIC 8	0.5 cm	2.5 cm	4.5 cm
Portex DIC 9	(-.4 cm)	1.5 cm	3.9 cm
BM Tracoe 6	0.8 cm	2.8 cm	4.8 cm
BM Tracoe 7	0.8 cm	2.7 cm	4.7 cm
BM Tracoe 8	0.8 cm	2.6 cm	4.7 cm
BM Tracoe 9	0.3 cm	2.3 cm	4.3 cm
Portex Ultra 6	1.5 cm	3.5 cm	5.7 cm
Portex Ultra 7	1 cm	3 cm	5.2 cm

Table 2: Estimation of initial catheter size

**Estimation of initial catheter size based on chest radiograph
(Distance from carina is measured below in centimeters)**

Portex Ultra 8	0.5 cm	2.6 cm	4.8 cm
Portex Ultra 9	0 cm	2.1 cm	4.3 cm

Table 2: Estimation of initial catheter size

WARNING: Reposition the Cadence mid-section hose and the heated wire circuit prior to taking a chest radiograph (x-ray) so that the heated wire circuit does not obscure the view of the chest cavity.

Deflate Tracheostomy Tube Cuff

To deflate cuff:

1. Insert a compatible luer tip syringe (syringe volume = 0cc) into the one-way valve.
2. Slowly pull up on the syringe plunger, until the pilot balloon is completely deflated. If the pilot balloon does not deflate, re-check the connection between the luer syringe and the pilot balloon, repeat the deflation process.

Catheter Insertion

Once the tracheostomy tube cuff is fully deflated, need for additional suctioning should be addressed. The 15 mm ventilator circuit connector T-piece or tracheostomy collar can then be removed from the tracheostomy tube. The non-fenestrated inner cannula of the fenestrated tube should be promptly removed and managed as per manufacturer recommendations. Where appropriate for the Qualified Tracheostomy Tube design, a fenestrated inner cannula should be inserted. The Cadence Transtracheal Catheter is removed from the sterile package and can be inserted with a gloved hand through the tracheostomy tube and into the trachea. Gently twirling in a circular fashion may facilitate insertion. If the catheter can not be easily passed, apply a small amount of water soluble jelly and try again. If the catheter still can not be easily passed, place the patient back on mechanical ventilation, properly inflate the cuff and monitor the patient's status. Evaluate for possible causes for difficulty in catheter insertion and consider another trial if cause or causes are identified and resolved.

Patient Monitoring

Patient monitoring is a critical function during Cadence Self-Breathing Trials. Patient monitoring has both device and clinical assessment components. For complete details see "Patient Monitoring" in Chapter 3 of the Operator's Manual.

Oxygen Saturation and Heart Rate

Pulse oximetry provides the necessary arterial oxygen saturation monitoring and offers heart rate monitoring, as well.

Airway Pressure Monitoring

Use of the Criterion 40 Airway Pressure monitoring device measures pressure within the tracheal tube lumen.

Hypoventilation/Hypercapnia

Devices available to monitor for hypoventilation/hypercapnia include:

- Inductance plethysmography via EKG or specialized belt
- Capnography
- Transcutaneous arterial carbon dioxide

Monitoring for hypercapnea requires observation by clinicians with experience in the management of prolonged mechanical ventilation, weaning, and self-breathing trials. Such a clinician must assess the patient at the bedside on a regular schedule during the Cadence self-breathing trial, as follows:

- Initiation: continuously for at least 15 minutes
- Day 1: at least every 30 minutes
- Days 2 and 3: at least every 60 minutes
- Days 4 and thereafter: at least every two to four hours

Arterial Blood Gas

ABG analysis should be considered at the end of the first self-breathing trial. In addition, ABG analysis should be obtained whenever clinically appropriate.

Delivered FiO₂

An oxygen analyzer should be used periodically to monitor and adjust delivered FiO₂.

Clinical Assessment

Clinical assessment is a critical function during Cadence Self-Breathing Trials. See “Clinical Assessment” Chapter 3 of the Operator’s Manual for complete details regarding criteria to identify tolerance to self-breathing trials.

- Bedside observational assessment by a trained clinician
- Objective measurement of vital signs
- Patients should be encouraged to talk
- Gross inspection and examination of the chest
- Abnormalities suggesting respiratory compromise should be identified

Contact Information

For information regarding the Cadence™ Self-Breathing System contact:
Respironics Customer Service
1-800-345-6443 or 724-387-4000
service@respironics.com

