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Suggested
protocol

CoughAssist 70 Series

CoughAssist T70 and CoughAssist E70 airway clearance devices

Please refer to the user manual for complete product description, including indications and contraindications for use. Once it has been determined that the CoughAssist treatment is clinically appropriate, the following may be used as a suggested protocol. Please review the entire protocol before initiating therapy.

This protocol is not intended as a substitute for advice from a licensed physician or other healthcare professional, and the prescription issued by the patient's physician should be followed.

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Indications

For use with patients unable to cough or clear secretions effectively due to reduced peak expiratory flow.

- Those who might benefit from the use of the CoughAssist T70/E70 include patients with an ineffective cough due to muscular weakness or dystrophy, myasthenia gravis, poliomyelitis, or other neurologic disorder with some paralysis of the respiratory muscles, such as spinal cord injury. It may also be used to treat ineffective cough due to other bronchopulmonary diseases, such as emphysema, cystic fibrosis, and bronchiectasis. It is effective for both trached and noninvasively ventilated patients.

- In pediatric patients who are able to perform a reproducible forced expiratory flow maneuver, a value less than 50% of predicted is an indication for CoughAssist therapy. PCF values > 270 LPM[1] have been established as the minimum level necessary to clear secretions in adults, but values for small children have yet to be validated and may be lower than the values for adults.[2]

Contraindications

- Any patient with a history of bullous emphysema

- Susceptibility to pneumothorax or pneumomediastinum

- Recent barotraumas

The above contraindications should be carefully considered before use.

Patients known to have cardiac instability should be monitored for pulse and oxygen saturation very closely.[3]

Warnings and cautions

Refer to the CoughAssist E70 or CoughAssist T70 user manual.

Patient preparation

The CoughAssist T70/E70 should be carefully introduced to the patient. If treating a pediatric patient, a parent or trusted caregiver should be involved, if possible. Allow the patient to become familiar with the mask, especially if they are unaccustomed to positive pressure therapy.

Implementation of CoughAssist T70/E70

- Attach the CoughAssist patient circuit to the CoughAssist output, including a bacterial/viral filter, smoothbore tubing, and an appropriate interface (mask, mouthpiece, or trach adapter). If a mask is used, it should be of appropriate size to provide a tight seal. When used with a trach, attaching directly to an inline suction catheter allows for easy removal of secretions from the top of the trach.

- Explain principles of the CoughAssist T70/E70 to the patient and the caregiver—deep inflation of the lungs followed by a forced exhalation of air aimed at removing secretions located in the central airways.

  Explain that the patient should relax so the air delivered by the CoughAssist T70/E70 slowly expands the lung and chest wall. After the deep breath is delivered, the exhalation phase will begin immediately.

  Instruct the patient to exhale fully during the exhalation phase.[2]

Features

Cough-Trak feature
An important characteristic of the device is its ability to trigger on the patient's inspiration to help synchronize the therapy with the patient. This is the Cough-Trak feature. Cough-Trak is available when the device is in Auto mode or Advanced Auto mode.

The pressure delivery sequence is synchronized with the patient's effort to inhale (pre-therapy breaths and cough therapy).

When the Cough-Trak setting is activated, therapy starts in the Pause phase until patient effort is detected.

- Evaluate inspiratory drive of the patient and select the Cough-Trak On/Off setting accordingly.

Oscillation feature
An Oscillation feature, available in Manual, Automatic and Advanced Auto modes, can be set either during one or both phases of the cough cycle (insufflation and/or exsufflation). The aim of the oscillations is to enhance loosening and mobilization of secretions, and improves bronchial drainage.

In Advanced Auto mode, the oscillations are also applied to any pre-therapy breaths (inhale only).

- Start at a high frequency (20 Hz) and low amplitude (1 cmH$_2$O) and adjust the settings to patient comfort.

- When using CoughAssist T70/E70 noninvasively, begin oscillations in the inhale phase and assess tolerance of the oscillations. If desired, oscillations may also be used in the exhale phase if tolerated.

Settings and modes

Manual mode

This mode may be used for initial acclimation to the CoughAssist T70/E70 and for titrating pressures and adjusting times prior to using the Automatic mode or the Advanced Auto mode.

- Begin with inspiratory pressures between +10 and +15 cmH_2O and expiratory pressures of between −10 and −15 cmH_2O to allow an introduction/acclimation to the device.[4] Set device inhale flow to the low setting.

- Press the "Therapy" button to start treatment. Position the appropriate interface to the patient. Start with a single cough cycle to allow for acclimation to the device. A cough cycle is one inspiration, one expiration, and then a pause, if needed. Move the Manual switch to the inhale position and hold for 1 to 3 seconds. Immediately move the Manual switch to the exhale position and hold for 0.5 to 2 seconds, then release the switch to the neutral position. Verify patient comfort and tolerance of the maneuver. Adjust timing to coordinate with the patient's breath rate and rhythm.[5]

- Continue with several cough cycles, 3 to 6 for pediatric patients and 4 to 6 for adults, in a session. If desired, a pause of 2 to 5 seconds between cough cycles may be used. Confirm continued tolerance of the maneuvers. A rest period of 30 to 60 seconds may be used before the session is repeated. Return the patient to his/her normal oxygen or ventilation settings during the rest period, if necessary. Perform at least 3 to 5 sessions for pediatric patients and 4 to 6 sessions for adults for each treatment.[2,5]

- Gradually increase the inspiratory and expiratory pressures. Adjust inhale flow, if needed, for patient comfort. Continually monitor the patient for comfort and tolerance. Positive pressure levels can be established by evaluation of chest wall expansion and auscultation for bilateral air entry.[5] The displayed insufflation volumes may be used to titrate inspiratory pressure levels to achieve adequate inspired volumes. The displayed values for peak cough flows may also be used to titrate expiratory pressure levels and to coach patient effort. Inspiratory and expiratory pressures of up to +/- 40 cm H_2O show the best results and are generally well tolerated.[2]

- Whenever possible, solicit feedback from the patient regarding pressures and inspiratory and expiratory times. For example, a gesture of up or down can be used to indicate whether to increase or decrease pressures or times.

- Subsequent treatment sessions can be initiated at previously established pressures, times and flow rates. These settings may also be entered as the presets for use with the Automatic Mode or the Advanced Auto Mode.

Automatic mode

Automatic mode provides a timing feature that will automatically trigger to inspiration and cycle to expiration instead of manually moving the switch. Inhale and exhale times entered into the device will replace manually moving the switch.

- Select Automatic mode on the display. If pressures, times, and flows were titrated using the Manual method, use those final values as starting values for the Automatic mode. If titrating in Automatic mode, use the same initial settings as explained previously in the Manual mode paragraph and adjust for patient comfort and tolerance. If Cough-Trak is enabled, the pause time is determined by the patient trigger.

- Position the patient interface to the patient and start therapy. Therapy will start automatically if Cough-Trak is turned off. If Cough-Trak is enabled, therapy will start as soon as the patient initiates a breath.

- The treatment can be temporarily suspended at any time by pressing the "Standby" key and returning the patient to his/her normal oxygen or ventilation settings.

- Adjustments to therapy can be made from the Settings screen while in "Standby" or "Therapy" mode.

Advanced Automatic mode

The Advanced Auto mode allows to set a number of successive insufflations prior to the cough therapy. Once the pre-therapy insufflations and cough therapy pattern has been established, the cycle can be repeated up to 10 times, with an option to end the sequence with a single insufflation cycle – as illustrated by the graph at right.

The Advanced Auto Mode can be programmed to simulate alternative airway clearance techniques (ACT), such as active cycle of breathing technique (ACBT), Autogenic Drainage (AD) or Airstacking.

Which patients?

All CoughAssist patients can use the Advanced Auto Mode.

The advanced auto mode – example

Cough-Trak	OFF
Pre-therapy breaths	4
Pre-therapy pressure	20 cmH_2O
Pre-therapy flow	Low
Pre-therapy time	2 sec.
Number of coughs	4
Inhale pressure	40 cmH_2O
Inhale flow	Medium
Inhale time	2 sec.
Exhale pressure	-40 cmH_2O
Exhale time	2 sec.
Oscillation	OFF
Number of cycles	3
Post-therapy breath	ON

Post-Therapy Breath (ON or OFF)

Pre-Therapy Breaths (OFF, 1 to 10)

Number of Coughs (1 to 15)

Number of Cycles (1 to 10)
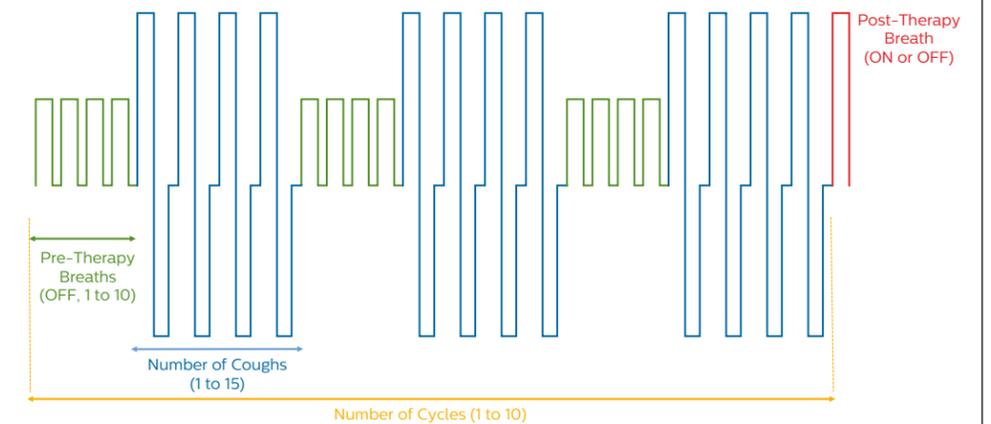
Which benefits?

- Patients with hyper reactive airways and prone to develop bronchospasm during the MI-E therapy can benefit from the pre-therapy breaths with low insufflation volume prior to the cough cycles.
- Patients who can airstack several insufflations promoting lung volume recruitment (to maximize their insufflation volume) prior to exsufflation, to help maximizing their peak cough flow outcome.
- Patients predisposing to the development of persistent atelectasis can benefit from the pre-therapy breaths with insufflation volume followed by breath hold to simulate the lung/thoracic/chest expansion therapy.
- Patients needing secretion mobilization from the peripheral airways can benefit from the pre-therapy breaths with varying insufflation volumes to simulate the alternative ACT.

Suggested settings for adult patient:

1. Select **Auto Advanced** on the display.
2. Set **Pre-Therapy Breaths** to 4 - or according to patient's needs.
3. Set **Pre-Therapy Flow** to Low - or according to patient's comfort.
4. Set **Pre-Therapy Pressure** level and time to 20 cmH_2O for 4 seconds and 2 second pause period (if Cough-Trak is disabled) or to achieve desired chest expansion and breath hold without excessive air leak or unintended gastric insufflation.
5. Set **Number of Coughs** to 4 – or according to patient's needs.
6. Set **Inhale Flow** to Medium, or according to patient's comfort.
7. Set the insufflation pressure and exsufflation pressure level to +/- 40 cmH_2O and 2 seconds for each insufflation, exsufflation and pause time (if Cough-Trak is disabled), or titrate the pressure level and time for patient's comfort and tolerance as you would do with the Manual or Automatic modes.
8. Set the **Number of Cycles** to 3 – or according to patient's needs.
9. The therapy may end with positive inhale pressure for patient's comfort and lung volume preservation[6], by setting **Post-Therapy Breath** to ON.
10. Start the simulated ACBT with patient performing in a short period of breathing control/relaxation cycle with 4~6 normal tidal volume breathing before initiating the Advanced Auto Mode. The duration of the breathing control/relaxation cycle should be adjusted as needed to prevent fatigue and hyperventilation.
11. Position the interface on the patient, and press 'Therapy' button to begin therapy. The CoughAssist T70/E70 delivers 4 pre-therapy breaths with set pressure and time to simulate the thoracic expansion exercise.
12. At the end of the 4th and last pre-therapy breath, the CoughAssist T70/E70 delivers 4 cough cycles.
13. At the end of the coughs, the CoughAssist T70/E70 repeats the above sequence (pre-therapy breaths followed by the cough cycles) 3 times, as set by the number of cycles.
14. Allow patient to rest and repeat the entire sequence as needed to achieve desired clinical outcome.

- Note that the treatment can be temporarily suspended at any time by pressing the "Standby" key and returning the patient to his/her normal oxygen or ventilation settings.

Treatment length and process

- A cough cycle is composed of one inspiration, one expiration, and a pause phase. A standard sequence consists of 3 to 6 consecutive cough cycles for pediatric patients and 4 to 6 consecutive cough cycles for adults, followed by a rest period of 30 to 60 seconds.

  Patients should be returned to their normal oxygen or ventilator settings during the rest period, if necessary. Sequences can be repeated 3 to 6 times if needed to clear secretions.[2,5]

- The CoughAssist T70/E70 maneuver may be ended on a positive pressure to preserve lung volume.[6] In the Advanced Auto mode, this can be achieved by enabling the post-therapy breath setting.

- Suction equipment should be available and visible secretions should be removed via suction from mouth, tracheostomy tube, or tubing, as needed.[5]

- A properly applied abdominal thrust or lower chest compression, coordinated with the exsufflation phase of the cough cycle, can enhance peak cough flows and secretion clearance.[7] In Manual mode, a foot pedal accessory can allow the clinician to free one hand, so the same clinician can manually deliver the therapy while applying the abdominal thrust.

Use with a tracheostomy

- Higher exhale pressures may be required to overcome the increased resistance of a tracheostomy or endotracheal tube. If the tracheostomy tube is cuffed, it is advised to have the cuff inflated for the CoughAssist T70/E70 treatment and to use a means for trapping any secretions that may potentially accumulate in the treatment circuit. Standard water traps, sputum traps, or extension tubing with corrugated inner walls can serve well for this purpose.

NOTE: The FDA defines pediatric in subgroups as follows: newborn—from birth to 1 month of age; infant—greater than 1 month to 2 years of age; child—greater than 2 to 12 years of age; adolescent—greater than 12 to 21 years of age.[8]

British Thoracic Society guidelines define young children as children under 10 years of age.[9]

References

1 Bach JR, Ishikawa Y, Kim H. Prevention of pulmonary morbidity for patients with Duchenne Muscular Dystrophy. Chest 1997;112: 1024-1028.

2 Fauroux B. et al. Physiological benefits of mechanical insufflation–exsufflation in children with neuromuscular diseases. Chest 2008;133: 161-168.

3 Bach JR. Update and perspective on noninvasive respiratory muscle aids. Part 2: the expiratory aids. Chest 1994;105: 1538−44.

4 CoughAssist Users Guide. J.H. Emerson Co.

5 Miske, Laura J., et al. Use of the mechanical in-exsufflator in pediatric patients with neuromuscular disease and impaired cough. Chest 2004;125: 1406-1412.

6 Jeremy Hull, Roona Aniapravan, Elaine Chan, et al. British Thoracic Society Guidelines for Respiratory Management of Children with Neuromuscular Weakness. Thorax July 2012 67: i1-i40.

7 Bach JR. Mechanical insufflation–exsufflation comparison of peak expiratory flow with manually assisted and unassisted coughing techniques. Chest 1993;104: 1553-1562.

8 Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices; March 24, 2014.

9 Guidelines for Respiratory Management of Children with Neuromuscular Weakness, British Thoracic Society. Thorax July 2012 67: i1-i40.