

PHILIPS

sense and simplicity

Trilogy100 and CoughAssist

The smart combination for neuromuscular disease patients



Neuromuscular diseases (NMDs) include both hereditary and acquired diseases of the peripheral neuromuscular system. They are diseases of the peripheral nerves (neuropathies and anterior horn cell diseases), the myoneural junctions (myasthenia gravis), or the muscles (myopathies) themselves. The pathology processes affecting the nerves and muscles can be anatomic, metabolic, electrical, inflammatory or immunologic, as well as idiopathic (unknown cause). These conditions cause muscle weakness, including respiratory muscles, but do not usually affect sensory functions.

Let's start with some clinical facts...

" ... **over 90% of episodes of respiratory failure** in patients with muscular dystrophy are caused by **ineffective coughing** during intercurrent chest colds. Most people with neuromuscular diseases still die prematurely or are hospitalized and undergo tracheotomy, because of failure to assist respiratory muscles to prevent respiratory failure."

*Bach JR. Mechanical insufflation/exsufflation: has it come of age?
A commentary. Eur Respir J 2003; 21:385-386*

Let's start with some clinical background and facts.

At present, the great majority of morbidity and mortality of NMD patients is due to respiratory complications of muscles weakness. That is why pulmonary management is the most critical aspect of treating NMDs – which is clearly illustrated by these quotes from Bach.

" Neuromuscular diseases (NMD) cause **muscle weakness that can affect [...] breathing, coughing [...]**, all of which can cause disability and compromise quality of life. [...]. **Weakness of breathing and coughing muscles, however, continues to be the major cause of repeated hospitalizations and loss of life.**"

Bach JR. Extract from the preface of the book "Management of Patients with Neuromuscular Disease"

" A growing number of children with NMD are surviving to adulthood with the aid of ventilatory support. **The combination of NIV with cough-assist techniques decreases pulmonary morbidity and hospital admissions.**"

*Simonds A. Recent Advances in Respiratory Care for Neuromuscular Disease
Chest 2006; 130:1879–1886*

Anita Simonds mentions in her article "Recent advances in respiratory Care for NMD" published in Chest in 2006 that [quote], emphasizing the need to combine coughassist and ventilation techniques to efficiently aid the respiratory muscles.

ADDITIONAL NOTE: Inspiratory and expiratory muscle aids are devices and techniques that involve the manual and/or mechanical application of forces to the body or intermittent pressure changes to the airway to assist inspiratory and expiratory muscle function.

There are three major goals of such intervention:

- To maintain lung and chest wall elasticity and to promote normal lung and chest wall growth for children
- To maintain normal alveolar ventilation
- To facilitate airway clearance



« Loss of respiratory muscle strength, with ensuing **ineffective cough** and decreased ventilation, **leads to pneumonia, atelectasis, and respiratory insufficiency** in sleep and while awake in DMD »

ATS Consensus Statement 2004: Respiratory Care of the Patient with Duchenne Muscular Dystrophy.

From the ATS consensus statement in 2004, we can see that not only the loss of respiratory muscle strength provokes hypoventilation, but also inefficient airway clearance, both phenomena leading to “pneumonia, atelectasis, and respiratory insufficiency in sleep and while awake in DMD”.

PHILIPS

With **Trilogy100 life support ventilator** and **CoughAssist mechanical in-exsufflator**, Philips Respironics offers a global solution for a better treatment and respiratory management of the neuromuscular diseases patients.



The diagram illustrates a transition from a fragmented state to a unified one. On the left, a house is constructed from three interlocking puzzle pieces: a green piece labeled 'Technology', a purple piece labeled 'Follow Up', and a teal piece labeled 'Education'. A blue arrow points to the right, where a solid blue house is shown. This house contains a white silhouette of a person and the text 'Patient Management' on its side, representing a complete and integrated solution.

6

From the previous slides and quotes, we see that a global respiratory management has to be considered for the NMD patients.

With the Trilogy100 life support and mechanical in-exsufflator CoughAssist, Philips Respironics is able to offer a global solution for a better treatment and respiratory management of these patients.

We offer a solution built around the three items Technology, Follow Up and Education, along with the knowledge of the physician/clinician to effectively and efficiently manage their patients.



Improve patient clinical condition

Technology

- High performance
- Effective ventilation
- Efficient airway secretion removal



Prevent exacerbation and chest infections

Follow Up

- Monitor ventilation and airway secretion encumbrance
- Assess efficacy & adjust therapy when necessary
- Follow disease progression



Provide optimal therapy

Education

- Properly use the equipment
- Understand the technology

PHILIPS

Trilogy100



8

Trilogy presentation

Technology *is critical for successful therapy*

"Making the right choice is important, since performance and patient comfort vary among devices. **Patient-ventilator synchrony is a key to the success of long-term Home NIV as dysynchrony causes patient intolerance."**

Performance Characteristics of 10 Home Mechanical Ventilation Pressure-Support Mode - Comparative Bench Study
Anne Battisti et al - *Chest* 2005



"The performance of the ventilators showed great variability, and depended upon the type of trigger (flow or pressure), type of circuit and patient profile. Differences were observed between the preset and measured airway pressure and between the tidal volume measured by the ventilator and on the bench. Leaks were associated with an inability to detect the patient's inspiratory effort or auto-triggering."

Performance of ventilators for non invasive positive-pressure ventilation in children
B. Fauroux et al - *ERJ* 2006



PHILIPS

Trilogy100 *features*



**Unique features
for unique patients**

**Because everyone
is different.**

Compact & easy to use

Auto-TRAK and AVAPS
Respironics proven technology

Non Invasive & invasive capabilities

Volume & pressure modes

For both children (> 5 kg) and adults

Up to 8 hours battery capacity

Weighs less than 5 kg



10

PHILIPS

Trilogy100 *features*



PHILIPS

Trilogy100 *features*

Display options
Limited patient use
Detailed clinical use

Data Management
Serial connector to
PSG
1GB SD card



Trilogy100 *configuration*

Delivery		Invasive & Non Invasive	
Application		Adults & Children	
Ventilation modes		Pressure	Volume
Therapy modes		CPAP S ST PC PC-SIMV	AC VC SIMV
Circuit configurations	Passive exhalation port 	Auto-Trak AVAPS ✓	Auto-Trak ✓
	Active exhalation valve 	✓	✓



13

PHILIPS

Respironics *technology*

Respironics well known technology
in leak circuit configuration



Single limb
circuit

Connects directly to a
-mask with integrated leak
-leak & a tracheotomy

Only one tube
-easy to connect
-easier to clean
-less noise
-safer

Advanced leak
compensation

In pressure & volume
-Auto-Trak
-AVAPS in pressure modes
-Estimated V_e & V_{te}
-Minimum PEP of 4 cmH_2O



14



Trilogy100

technology summary

Respironics *proven technology*

Performance	Versatility	Simplicity
<ul style="list-style-type: none">• Advanced leak compensation• Auto-Trak algorithm• AVAPS hybrid ventilation• DirectView management software	<ul style="list-style-type: none">• Configurable to meet patient ventilation needs• Invasive & non invasive• Power options• Diagnostic interfacing	<ul style="list-style-type: none">• Intuitive operation• Patient friendly• Easy to maintain• Safe



PHILIPS

Enhanced *clinical assessment*

Polysomnographs

- Ventilation curves from the Trilogy100 in addition to the PSG signals
- Assess ventilation efficacy to adjust parameters and provide accurate diagnosis



DirectView

- Manage patient ventilation therapy



PHILIPS

DirectView *data management software*



Is my patient compliant?
1 yr compliance data



How does patient ventilation progress?
30 days daily trends
1 year long term trends



Look at trends first to then zoom in abnormal periods
72 hrs wave forms:
• Pressure
• Flow
• Leak
• Tidal Volume
• BPM



To get the values
1 yr Statistics



17

PHILIPS

CoughAssist



18

CoughAssist presentation

PHILIPS

Technology *is critical for successful therapy*

CoughAssist has been clinically proven to:

- Increase peak cough expiratory flow by more than fourfold

McCool DF. Nonpharmacologic airway clearance therapies: AACP evidence-based clinical practice guidelines. Chest. 2006; 129:250-259.

- Reduce recurrent respiratory infections in patients with respiratory weakness from neuromuscular disease

Chatwin M. Cough augmentation with mechanical insufflation/exsufflation in patients with neuromuscular weakness. Eur Respir J. 2003;21:502-508.

Miske LJ. Use of the mechanical in-exsufflator in pediatric patients with neuromuscular disease and impaired cough. Chest. 2004;125:1406-1412.



Airway Secretion Clearance

Loosening

Devices that help loosening secretions in case of thick phlegm so that the patient **who can cough** can more easily clear his secretions

Assisted Cough

Replace a cough when **patients cannot cough** whether the secretions are thick or loose, it does not change the structure of the phlegm but just makes a cough

PHILIPS

CoughAssist *features*



It coughs when patients can't

Assists patients with clearing retained secretions
Mainly, **Neuromuscular Diseases** and **Spinal Cord Injuries**

Simulates a cough

by applying a positive pressure (deep insufflation) to the airway followed by a rapid shift to a negative pressure to produce expiratory flow from the lungs and effectively remove secretions

Non invasive technique

Can be given via facemask, mouthpiece, endotracheal or tracheostomy tube

Approved for adult and pediatric populations



21

Mainly, **Neuromuscular Diseases** (Muscular Dystrophy (Duchenne), Myasthenia gravis, Poliomyelitis, Amyotrophic Lateral Sclerosis (ALS), Spinal Muscular Atrophy (SMA)) and **Spinal Cord Injuries**

MI-E is the only current therapy that mechanically assists the expulsive phase of coughing, which is critical in airway clearance.

MI-E is able to clear medium and small bronchi in addition to central airways and both the left and right airways.

PHILIPS

CoughAssist *features*



Two models: Automatic and Manual

Positive Pressure: settable from 5 to 60 cmH₂O

Negative Pressure: settable from -5 to -60 cmH₂O

Inhale, Exhale, Pause Times: 0 to 5 sec.

Weight: 11 Kg automatic, 9.3 Kg manual

Maximum Expiratory Flow: 10 L/S

No routine preventive maintenance required
1 year warranty



22

Inhale pressure control knob = varies the inspiratory pressure between 50-100% of the exhale pressure

Unequal pressures may be prescribed to maximize the exsufflation phase while minimizing the stretch to the intercostal muscles during the insufflation phase.

Inhale flow control knob = adjust to low (3.3 LPS) or high (10 LPS)

→set as per patient comfort

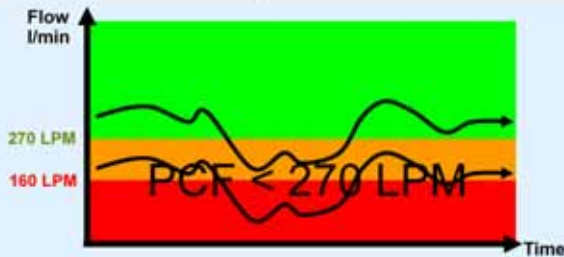
→lower setting may be preferable for patients with flaccid upper airways (i.e. ALS)

CoughAssist *indications for use*

Any patient unable to cough or clear secretions effectively due to reduced peak cough expiratory flow

PCF < 160 LPM (Bach JR et al, Chest 1996)

PCF < 240 – 270 LPM (ATS Consensus statement 2004 / Bach JR et al, Chest 2003)



- Max Expiratory Pressure < 45-60 cmH₂O (40-50 % theory)
ATS Consensus statement 2004; G Lopes et al. Eur Respir J 2000; 16: 37s
- Forced Vital Capacity < 1,5-2 L (30-50% theory)
JR Bach et al. Chest, 1996; 2000; G Lopes et al. Eur Respir J 2000; 16: 37s



CA is to be used when inspiratory muscles and expiratory muscles do not provide an efficient cough and other techniques are inefficient, or balance action/fatigue is too high.

160 LPM is the minimum PCF value needed to clear airway secretions from central airways. In patients with unassisted PCF < 160 LPM, mechanical assisted cough is required.

But a PCF threshold of 160 LPM do not guarantee adequate airway clearance in case of sudden respiration infection. Indeed, these patients are likely to suddenly deteriorate in case of acute viral illness (acute viral illness is associated with a reduction of vital capacity). In this case, PCF decreases below 160 LPM, the patient decompensates and has to be admitted to ICU.

This is why a PCF value of 270 LPM has been identified as a threshold for patients to be taught assisted cough techniques. In case of a sudden deterioration of the respiratory function, the patient stays above the critical threshold of 160 LPM.

CoughAssist *contraindications*

Bullous emphysema

Pneumothorax or pneumo-mediastinum

Acute Lung Injury (ALI) / Acute Respiratory Distress Syndrome (ARDS)

Patients with hemodynamic instability without appropriate monitoring

Acute pulmonary edema

Recent barotrauma

Some of Tracheomalacia and Bulbar ALS




- Bullous emphysema: emphysema associated with large bullae, type of COPD involving damage to the air sacs (alveoli) in the lungs (destruction of lung tissue).
- Pneumothorax is caused by accumulation of air or gas in the pleural cavity, occurring as a result of disease or injury.
- Pneumomediastinum is a condition in which air is present in the mediastinum (structure of the thorax).
- Acute pulmonary edema is swelling and/or fluid accumulation in the lungs.
- Tracheomalacia: disease affecting the upper airways structure, becoming flaccid, soft – possibility to collapse if high negative pressure is applied.
- Bulbar patients cannot control their glottis, possibility of collapsing the upper airways

PHILIPS

CoughAssist *benefits*

- Increase Peak Cough Expiratory Flow
- Decrease recurrent infections and exacerbations
- Decrease rehospitalization rate
- Decrease or avoid suctioning
- Avoid tracheostomy on NIV patients
- Increase quality of life



25

Endotracheal suctioning is a component of bronchial hygiene therapy and mechanical ventilation and involves the mechanical aspiration of pulmonary secretions from a patient with an artificial airway in place - **Invasive procedure, very uncomfortable for the patient** - Removes secretions but does not loosen them.

Suctioning (Invasive Secretion Clearance) may:

- Damage tracheal mucosa (tracheal bleeding), impair ciliary function or destroy cilia
- Clear left lung poorly due to angle of left bronchus
- Increase production of secretions
- Exert vagal response and decrease heart rate
- Increase intracranial pressure
- Cause hypoxemia

CoughAssist *typical treatment* (1/2)

- 1 cycle consists of Inhale, Exhale, Pause
- 4 to 5 cough cycles given in rapid succession (1 sequence)
- Patient rests for 20 – 30 seconds (spontaneous breathing)
- During rest, clear secretions that are visible in the mouth, throat or tracheostomy tube
- Repeat above sequence 4 – 6 times or until secretion expelled

A CA cycle is made up of an inhalation phase, an exhalation phase and a pause phase.

One treatment consists of about 5 cycles of MI-E or MAC (Mechanical Assisted Cough, i.e. use of the CA in combination with abdominal thrust with the exsufflation) followed by a short period of normal breathing or ventilator use to avoid hyperventilation.

When delivered via a tracheostomy tube, the cuff if present should be inflated. Briefly deflate cuff to obtain secretion from above.

1. Inform patient about CoughAssist prior to use
2. Have the head of the patient on a support and patient a little bit leant backwards to open the chest and thoracic cage
3. If face mask, apply it securely
4. Adjust mask to eliminate leak
5. Coordinate with patient breathing pattern

For the first session, it is important to start with low pressures, non therapeutic pressures.

CoughAssist *typical treatment* (2/2)

- Possibility to use abdominal and chest compression during expiration
- Typical pressure settings: +40cmH₂O/-40cmH₂O, but to be adjusted to the individual patient's needs
- Frequency of sessions according to case history
- Best before meals and at bedtime
- Home pulse oximetry is useful to monitor the effectiveness of airway clearance



Unless contraindicated, an assisted cough maneuver will usually increase the PCF by 20%. The assisted cough maneuver is applied when lungs are full at the onset of the CA negative pressure. Pressures below 40 cmH₂O may be inefficient, The use of the home pulse oximetry to monitor the effectiveness of airway clearance is a recommendation of the ATS, from the consensus statement from 2004 about the **Respiratory Care of the Patient with Duchenne Muscular Dystrophy**.

CoughAssist *primary reference studies*

Simonds AK. Recent Advances in Respiratory Care for Neuromuscular Disease **Chest**. Dec 2006; 130: 1879-1886.

Miske LJ, Hickey EM, Kolb SM, Weaver DJ, Panitch HB. Use of the Mechanical In-Exsufflator in Pediatric Patients with Neuromuscular Disease and Impaired Cough. **Chest**. April 2004; 125(4):1406-1412.

Sancho J, Servera E, Diaz J, Martin J. Efficacy of Mechanical Insufflation-Exsufflation in Medically Stable Patients with Amyotrophic Lateral Sclerosis. **Chest**. April 2004;125(4):1401-1405.

American Thoracic Society Consensus Statement (Approved by the ATS Board of Directors March 2004) Respiratory Care of the Patient with Duchenne Muscular Dystrophy. **Am J Respir Crit Care Med**. 2004; 70: 456-65

Winck JC, Gonçalves MR, Lourenço C, Viana P, Almeida J, Bach JR. Effects of Mechanical Insufflation-Exsufflation on Respiratory Parameters for Patients With Chronic Airway Secretion Encumbrance. **Chest**. Sept 2004;126: 774-780.

Rancho J, Servera E, Martin J, Vergara P. Mechanical Insufflation-Exsufflation vs. Tracheal Suctioning via Tracheostomy Tubes for Patients with Amyotrophic Lateral Sclerosis: A Pilot Study. **American Journal of Physical Medicine & Rehabilitation**. October 2003; 82(10): 750-753.

Chatwin M, Ross E, Hart N, Nickol AH, Polkey MI, Simonds AK. Cough Augmentation with Mechanical Insufflation/Exsufflation in Patients with Neuromuscular Weakness. **Eur Respir J**, March 2003; 21(3): 502-508.

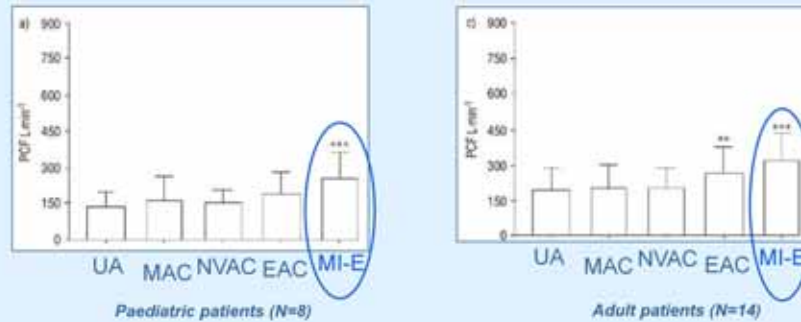
Bach JR. Mechanical insufflation-exsufflation. Comparison of peak expiratory flows with manually assisted and unassisted coughing techniques. **Chest**. 1993; 104(5): 1553-62.

McCool DF, Rosen M. Nonpharmacologic Airway Clearance Therapies: ACCP Evidence-Based Clinical Practice Guidelines. **Chest**. Jan 2006; 129: 250S-259S.

There are lots of clinical studies published about CoughAssist, mainly about NMD, both adults and pediatrics.

Cough augmentation with mechanical insufflation/exsufflation in patients with neuromuscular weakness

Chatwin et al, Eur Respir J, 2003



Mechanical insufflation-exsufflation produces a greater increase in peak cough flow than other standard cough augmentation techniques in adults and children with neuromuscular disorders.

UA=Unassisted Cough; MAC=Manual Assisted Cough; NVAC=Noninvasive Ventilator Assisted Cough; EAC=Exsufflation Assisted Cough; MI-E=Mechanical Insufflation-Exsufflation

This study by Chatwin and coworkers has been very important in the development of the knowledge of the CoughAssist technique in Europe.

It compares different techniques of cough augmentation in patients with neuromuscular weakness, the studied group comprising some adults (31yrs old +/- 13) and some pediatric (14yrs old +/- 2) patients.

Twenty-two patients aged 10–56 yrs (median 21 yrs) with neuromuscular disease and 19 age-matched controls were studied. Spirometry was performed and respiratory muscle strength measured. Peak cough flow was recorded during maximal unassisted coughs, followed in random order by coughs assisted by physiotherapy, noninvasive ventilation, insufflation and exsufflation, and exsufflation alone. Subjects rated strength

of cough, distress and comfort on a visual analogue scale.

- UA = unassisted cough
- MAC = standard physiotherapy assisted cough
- NVAC = cough after inspiration supported by a noninvasive positive pressure ventilator
- EAC = mechanical exsufflation-assisted cough with delivery of negative pressure initiated manually at the end of inspiration
- MI-E = use of the CoughAssist

The greatest increase in peak cough flow was observed with mechanical

insufflation/exsufflation at 235 \pm 111 LPM. All techniques showed similar patient acceptability. Mechanical insufflation/exsufflation produces a greater increase in peak cough flow than other standard cough augmentation techniques in adults and children with neuromuscular disease.

Philips Respronics *support*



Expertise

Clinical specialists & training programs

Supporting materials & media to

- Train clinical staff/technicians on the technology (and follow up software for Trilogy100)
- Support you with the technology in your daily work

Workshops & Symposium

Learn & share best practice/research



PHILIPS

Conclusion *Trilogy100/CoughAssist*



- Full Life Support ventilator featuring Philips Respiroics technology
- NIV and IV, Pressure and Volume, for adults and children (> 5 Kgs)

The Smart Combination for the Respiratory Management of the Neuromuscular Disease Patients

- Non invasive and flexible technique
- For adults and pediatrics

