

THE BREATHER™

ONE DEVICE – MANY THERAPIES



PROTOCOL BY USE CASE

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This guide was created to give you the general **Breather** protocol along with patient specific use cases for personalized treatment plans. If you are unsure about the optimal use case to choose, watch the therapist only in-service video (pnmedical.com/go) or reach out to us by phone or email: 877-414-4449 or Care@pnmedical.com.

Section I of this guide contains links for you and your patients to watch our easy to follow, best in industry, [video protocol training series](#). It demonstrates proper use and cleaning, and explains the general treatment protocol in detail. It also includes how to's on proper breathing, posture, and more to help motivate **Breather** users to adhere to the plan you design for them.

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I: INTRODUCTION, GENERAL PROTOCOL & VIDEO VERSION

DESCRIPTION

The Breather is a drug-free respiratory device that promotes respiratory muscle training (RMT) by breathing through different sized apertures, thereby increasing respiratory muscle strength. As resistance is applied during both phases of the breath cycle, **The Breather** increases inspiratory as well as expiratory muscle strength by causing hypertrophy of the respiratory muscle fibers, and thickening and increased velocity of the diaphragm. RMT also improves laryngeal function, supporting speech quality, intensity and swallow efficiency [1-3].

PATIENT IDENTIFICATION

Patients experiencing abnormal respiratory function impacting activities of daily living including: dyspnea and/or activity intolerance as well as decreased breath support for phonation and safe swallowing should be considered for RMT.

Target Patient Groups [4]:

- Respiratory (COPD, asthma, chronic lung disease)
- Cardiac (congestive heart failure, coronary artery disease, hypertension)
- Neuromuscular (Parkinson's, multiple sclerosis, myasthenia gravis, Pompe's)
- Pre-and post-operative (major thoracic and abdominal surgery, neurosurgery)
- Healthy ageing

Note: Successful application does require patient cooperation and motivation. In patients who have experienced an acute exacerbation, or chest infection, clinical judgement should be applied regarding the risk of provoking excessive fatigue of the inspiratory muscles. In this situation, reducing the intensity and/or frequency of RMT may be prudent.

Note: RMT has proven successful in pediatric use and can be applied with due clinical judgement [5-7]. Caution: **The Breather** is not a toy and small parts may pose a choking hazard to children.

CLINICAL EVIDENCE

The effectiveness of RMT is supported by a growing body of scientific and medical evidence across a steadily increasing range of diseases and disorders. For a collection of clinical evidence, including frequent updates and discussions of emerging data, please see references attached to this document or visit pnmedical.com/blog.

COMMON PATIENT CHALLENGES

Potential adverse events include transient light headedness or dizziness at training onset, mild fatigue, and issues with finger fatigue.



CONTRAINDICATIONS

During initial training, we recommend careful monitoring for episodes of acute exacerbation or excessive fatigue. Caution is advised before initiation of therapy for: active hemoptysis, untreated pneumothorax, recent esophageal surgery, acute upper airway stenosis (true vocal fold mass, vocal fold paralysis in adducted position, sub-glottic stenosis), recent oral, facial or skull trauma / surgery, acute sinusitis, epistaxis, hemodynamic instability, tympanic membrane rupture or acute middle ear pathology (otitis, labyrinthitis).

GETTING STARTED USING THE BREATHER

Patient & Clinician Training Videos

Client direct training videos and resources are available at pnmedical.com/start

Additional training videos available at pnmedical.com/training

Equipment

- One **Breather** per patient (single patient use - permanent marker to label with patient's name)
- Pulse Oximeter and/or manometer is optional.
- Watch with second hand to monitor respiratory rate.
- Soapy water to clean **The Breather** per manufacturer's instructions on package insert.
- Nose clips (single patient use) as indicated to limit air flowing through nose during RMT.

Before you begin

- If you or your patient has access to the Internet, we recommend to watch our easy to follow free video training. <http://www.pnmedical.com/start>
- Also or if no access to Internet, read the manufacturer's instructions on package insert.

NOTE - The online training is more in-depth than the manufacturer's instructions included.
- If the patient is on continuous oxygen, ensure that it is on during RMT. If oxygen is ordered by PRN, use it if patient becomes short of breath as RMT is exercised.
- Introduce **The Breather** to the patient with explanation of RMT. Demo with your own **Breather**.
- Position patient to maximize diaphragmatic breathing.
- Begin with the easiest settings by rotating both inhale and exhale dials so the #1 aligns with the arrow at the top of **The Breather**.

NOTE - inhale and exhale dials function independently.



FIRST SESSION

- Instruct the patient to hold mouthpiece with lips, not teeth as this may cause undue jaw pressure and inadequate lip seal.
- Ask patient to breath in and out through the mouthpiece (not the nose). Instruct to inhale deeply and forcefully for 2-3 seconds, slight pause (under a second), then exhale forcefully for 2-3 seconds.
- Cue the patient to listen for a strong ‘wind’ sound for audio biofeedback as a strong, audible airflow should be heard for inhale and exhale. It’s most helpful for the therapist to demonstrate with their own **Breather**.
- The patient should slightly remove **The Breather** from the mouth to swallow normally to prevent saliva buildup in **The Breather**.
- If the patient has difficulty NOT breathing through their nose, it may be helpful to pinch the nose with fingers during initial instruction.
- If necessary or preferred, a nose clip may be used.
- Monitor vital signs as needed including oxygen saturation (using a pulse oximeter) as well as overt signs of hypoxemia.
 - If extreme respiratory distress during or after RMT occurs, avoid re-initiation of RMT until medical clearance can be obtained.
- Obtain baseline for tolerated breaths per set and number of sets.
 - You should ask your patient frequently for feedback including:
 - How do you feel? Do you feel out of breath or lightheaded?
 - You should also observe:
 - Each inhale / exhale should be able to be forcefully maintained for 2-3 seconds.
 - Inspiratory resistance should cause an outward movement of the stomach on all inhalations. If inward movement of the stomach occurs on a few, but not all inhalations, this could be a sign of fatigue; the patient should rest more between breaths or sets, or decrease the setting temporarily.
 - Expiratory resistance should not cause puffing of the cheeks. If patient cannot eliminate this, the patient may need to rest more between breaths or decrease setting temporarily. The therapist may also hold patient’s cheeks or have patient hold his cheeks. (A demo may be necessary.)
- **NOTE** – Transient light headedness may occur at training onset
 - This is a normal response to a forced inspiratory/expiratory maneuver. It is short lived and self limited. If experienced, the subject may resume the session after such symptoms have resolved. In order to optimize patient comfort, performance and safety we recommend he or she uses **The Breather** while sitting comfortably on a chair.



II: USING THE BREATHER FOR RESPIRATORY DISEASE

Respiratory muscle weakness is a major contributor to the development of dyspnea and exercise intolerance. It is also associated with respiratory muscle disorders prevalent in COPD and asthma, contributing to clinical decline and reduced health-related quality of life [8].

RMT using **The Breather** alleviates the symptoms of diverse respiratory diseases, and improves exercise capacity, dealing with activities of daily living, and quality of life [2,9].

PURPOSE FOR USE

- Strengthens inspiratory muscles (diaphragm, external intercostals, accessory muscles of neck) and expiratory muscles (internal intercostals, abdominals)
- Promotes diaphragmatic breathing
- Decreases shortness of breath
- Reduces hyperinflation
- Reduces bronchodilator use

SPECIFIC CLINICAL BENEFITS

- Increased maximal inspiratory and expiratory pressure (P_Imax, P_Emax) [10]
- Reduction of dyspnea (BORG scale) [11]
- Increased exercise tolerance (6MWT) [11]
- Reduced hyperinflation and improved inspiratory fraction and capacity (IC, IF) [11,12]
- Increased peak inspiratory and expiratory flow (PIF, PEF) [5,13]
- Improved oxygen saturation [14]
- Improved diaphragmatic function [1]
- Improved delivery and distribution of inhaled medication [13]
- Reduced frequency of exacerbations [15]
- Reduced hospitalization rate [9,15]

ADDITIONAL BENEFITS

- Improved quality of life (QOL) [11]
- Reduced hospitalization and healthcare requirements [15]
- Reduced risk of death [12]

RECOMMENDED PROTOCOL:

NOTE – these are protocol recommendations based on clinical evidence for RMT. These should not replace clinical judgement by the therapist and still need to be tailored to each patient's case, status, and preferences.



Please carefully read and follow the general guidelines for **GETTING STARTED** and **FIRST SESSION**, or watch the free online training lessons (<http://www.pnmedical.com/start>).

RMT target:

6 days a week. 2 sessions per day (mornings and evening). 2 sets of 10 breaths per session.

Intensity:

At least 60% of maximum effort. The correct setting should allow you to tolerate a set of 10 breaths, but it should feel challenging without causing fatigue. Note that the settings for inhalation and exhalation need to be determined and set independently.

If using a manometer, the correct setting is around 60% to 80% of maximum inspiratory/expiratory pressure (MIP/MEP). This roughly corresponds to #6-8 on The Breather Effort Scale.

Ongoing therapy:

After maintaining training at baseline for approximately 1 week, increase resistances. When resistance is increased, repetitions may decrease initially then gradually increase again throughout the week.

Documenting progress:

Keep an RMT diary to note number of reps and sessions, settings, and other comments. You can download the free training journal at pnmedical.com/start or download the free Breather Coach app to track sessions.

THE BREATHER.
START DATE: ___/___/___



TRAINING JOURNAL

CHECKOUT TRAINING VIDEOS:
PNMedical.com/Start

PROTOCOL:

__ sets of __ reps per session, __ sessions per day __ days per week with effort maintained *in the zone*.

WEEK 1	SUN		MON		TUES		WEDS		THURS		FRI		SAT	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
DIAL SETTINGS	/	/	/	/	/	/	/	/	/	/	/	/	/	/
REPS/SETS COMPLETED	/	/	/	/	/	/	/	/	/	/	/	/	/	/
EFFORT <i>in the zone</i> ?														

During respiratory Muscle Training with **The Breather**, you will experience the greatest benefit if you keep your effort level *in the zone*. For more information on this check out the training videos at PNMedical.com/Start



WWW.PNMEDICAL.COM

See Section 7: Maintaining Respiratory Muscle Strength, for further details.

III: USING THE BREATHER FOR CARDIAC DISEASE

Cardinal manifestations of heart failure include dyspnea, fatigue and exercise intolerance. Respiratory muscle weakness is a major contributor to these symptoms [11,16].

RMT using **The Breather** improves dyspnea and exercise intolerance by improving respiratory muscle strength and oxygen supply, as well as cardiac autonomy and blood flow to the limbs to further support regained activity. RMT can further reduce the risk of cardiovascular disease by reducing your blood pressure [11,17-19].

PURPOSE FOR USE

- Strengthens inspiratory muscles (diaphragm, external intercostals, accessory muscles of neck) and expiratory muscles (internal intercostals, abdominals)
- Promotes diaphragmatic breathing
- Decreases shortness of breath
- Improves blood flow to resting and exercising limbs
- Delays metaboreflex activation

CLINICAL BENEFITS

- Increased maximal inspiratory and expiratory pressure (P_Imax, P_Emax) [10]
- Reduction of dyspnea (BORG scale) [11]
- Increased exercise tolerance (6MWT) [11]
- Reduced hyperinflation and improved inspiratory fraction and capacity (IC, IF) [11,12]
- Increased peak inspiratory and expiratory flow (PIF, PEF) [5,13]
- Improved oxygen saturation [14]
- Improved cardiac autonomy and sympathetic nerve activity [11,17]
- Reduced systolic and diastolic blood pressure [19]

ADDITIONAL BENEFITS

- Improved quality of life (QOL) [11]
- Reduced hospitalization and healthcare requirements [15]
- Reduced risk of death [12]

RECOMMENDED PROTOCOL:

NOTE – these are protocol recommendations based on clinical evidence for RMT. These should not replace clinical judgement by the therapist and still need to be tailored to each patient's case, status, and preferences.



Please carefully read and follow the general guidelines for **GETTING STARTED** and **FIRST SESSION**, or watch the free online training lessons (<http://www.pnmedical.com/start>).

RMT target:

6 days a week. 2 sessions per day (mornings and evening). 2 sets of 10 breaths per session.

Intensity:

Approximately 30% of maximum effort. The correct setting should allow you to comfortably tolerate a set of 10 breaths without causing dyspnea. Note that the settings for inhalation and exhalation need to be determined and set independently.

If using a manometer, the correct setting is around 30% of maximum inspiratory/expiratory pressure (MIP/MEP). This roughly corresponds to #3 on The Breather Effort Scale.

Ongoing therapy:

Increase settings according to increased respiratory muscle strength, but do not increase intensity.

Documenting progress:

Keep an RMT diary to note number of reps and sessions, settings, and other comments. You can download the free training journal at pnmedical.com/start or download the free Breather Coach app to track sessions.

See Section 7: Maintaining Respiratory Muscle Strength, for further details.



IV: USING THE BREATHER FOR NEUROMUSCULAR DISEASE

Neuromuscular diseases such as Parkinson's, Myasthenia Gravis or muscular dystrophies are often associated with peripheral and respiratory muscle weakness, which may progress during the course of the disease. Depending on the disease, respiratory muscle weakness leads to speech and swallow problems, reduced speech intensity, as well as respiratory impairment [20,21].

RMT using **The Breather** improves speech, swallow and cough function, reduces penetration and aspiration, and strengthens respiratory muscles.

Please note that in muscular dystrophies, RMT should be carefully monitored with consideration to avoid overtraining.

PURPOSE FOR USE

- Strengthens inspiratory muscles (diaphragm, external intercostals, accessory muscles of neck) and expiratory muscles (internal intercostals, abdominals)
- Improves movement of the hyolaryngeal complex
- Generates improved airflow through vocal folds
- Improves respiratory support for safe swallow function
- Improves protective cough and assists in airway clearance
- Promotes diaphragmatic breathing
- Decreases shortness of breath
- May slow progression of respiratory myopathy

CLINICAL BENEFITS

- Increased maximal inspiratory and expiratory pressure (P_Imax, P_Emax) [10,22]
- Potential increase in lung capacity [22]
- Reduced respiratory load perception [23]
- Potential deceleration of respiratory muscle strength decline [24]
- Improved laryngeal function for speech and swallow [20,25]
- Improved reflex cough for better pulmonary hygiene [25]
- Improved diaphragmatic function, supporting breathing and speech quality and intensity [1]



ADDITIONAL BENEFITS

- Improved quality of life (QOL) [11]
- Reduced hospitalization and healthcare requirements [15]
- Reduced risk of death [12]

RECOMMENDED PROTOCOL:

NOTE – these are protocol recommendations based on clinical evidence for RMT. These should not replace clinical judgement by the therapist and still need to be tailored to each patient’s case, status, and preferences.

Please carefully read and follow the general guidelines for **GETTING STARTED** and **FIRST SESSION**, or watch the free online training lessons (<http://www.pnmedical.com/start>).

RMT target:

Work up to 5 sets of 5 breaths per session, twice a day, 6 days per week, or as tolerated.

Intensity:

Approximately 60% of maximum effort. The correct setting should allow you to tolerate a set of 10 breaths, but it should feel challenging without causing fatigue. Note that the settings for inhalation and exhalation need to be determined and set independently.

If using a manometer, the correct setting is around 60% of maximum inspiratory/expiratory pressure (MIP/MEP). This roughly corresponds to #6 on The Breather Effort Scale.

Ongoing therapy:

Increase settings according to increased respiratory muscle strength, but do not increase intensity (ie keep intensity at 60% of MIP/MEP).

Documenting progress:

Keep an RMT diary to note number of reps and sessions, settings, and other comments. You can download the free training journal at pnmedical.com/start or download the free Breather Coach app to track sessions.



V: USING THE BREATHER BEFORE & AFTER SURGERY

Postoperative pulmonary complications (PPC) such as pneumonia and atelectasis are the leading cause of morbidity and mortality after major cardiac or abdominal surgery. PPC increase the duration of hospitalization and healthcare costs.

Perioperative RMT using **The Breather** can reduce the risk of PPC, morbidity and mortality and decrease the length of stay [26,27].

In addition, RMT reduces the risk of endotracheal intubation, and can support liberation from mechanical ventilation. RMT reduces time to liberation, and increases liberation success [28-30].

PURPOSE FOR USE

- Strengthens inspiratory muscles (diaphragm, external intercostals, accessory muscles of neck) and expiratory muscles (internal intercostals, abdominals)
- Promotes diaphragmatic breathing
- Improves protective cough and assists in airway clearance
- Improves respiratory support for safe swallow function
- Improves movement of the hyolaryngeal complex

CLINICAL BENEFITS

- Increased maximal inspiratory and expiratory pressure (P_Imax, P_Emax) [10]
- Improved diaphragmatic function and increased thickness [1,31]
- Improved oxygen saturation [14]
- Reduced systolic and diastolic blood pressure [19]
- Improved laryngeal function for speech and swallow [20,25]
- Improved reflex cough for better pulmonary hygiene [25]

INPATIENT SPECIFIC BENEFITS

- Reduced duration of mechanical ventilation [28]
- Increased success rate for liberation from mechanical ventilation [30]
- Reduced risk of postoperative pneumonia and atelectasis [26]
- Reduced hospital length of stay [16-27]
- Reduced hospital mortality [29]
- Reduced risk of endotracheal intubation [29]



ADDITIONAL BENEFITS

- Improved quality of life (QOL) [11]
- Reduced hospitalization and healthcare requirements [15]
- Reduced risk of death [12]

RECOMMENDED PROTOCOL:

NOTE – these are protocol recommendations based on clinical evidence for RMT. These should not replace clinical judgement by the therapist and still need to be tailored to each patient’s case, status, and preferences.

Please carefully read and follow the general guidelines for **GETTING STARTED** and **FIRST SESSION**, or watch the free online training lessons (<http://www.pnmedical.com/start>).

Preoperative RMT:

Start RMT using **The Breather** \geq 2 weeks before surgery at highest tolerated setting, with incremental increase if BORG $<$ 5, 2 x 10 breaths twice (or more) per day, in addition to standard care. Re-start RMT at tolerated setting after surgery upon extubation.

Postoperative RMT:

Start RMT using **The Breather** as soon as cleared surgically and/or upon extubation at the highest tolerated setting. Work up to 2 sets of 10 breaths at least twice a day, 7 days per week.

Liberation from mechanical ventilation:

For difficult to wean patients, work up to 2 sets of 10 breaths with 1-2 minutes of rest between sets twice (or more) per day, at the highest comfortable setting, for 7 days per week. Evaluate weaning success with daily spontaneous breathing trials. If **The Breather** can not be used orally during times off ventilation, it can be directly attached to the tracheotomy tube once the patient is capable of breathing against resistance.

NOTE – Use of **The Breather** is **not** recommended for patient with endotracheal intubation!

Intensity:

As tolerated.

Ongoing therapy:

Continue use during ICU and hospital stay, working up to the recommended protocol for respiratory or cardiac use, as indicated (see Section 2 or 3 of this Protocol). Encourage use after discharge for continued benefit.



VI: USING THE BREATHER DURING HEALTHY AGEING

During the normal process of ageing, respiratory muscles decline in mass and function, reducing physical activity and functional independence, and contributing to sarcopenia and deterioration of gait, which can increase the risk of falling.

Respiratory muscle weakness in the elderly also causes loss of the elastic lung recoil, reduced airway clearance capacity, and decreased responsiveness to hypercapnia and hypoxemia [29-31].

Respiratory muscle training (RMT) using **The Breather** can improve respiratory muscle strength, allowing for increased physical activity and exercise tolerance, and improved respiratory function.

PURPOSE FOR USE

- Strengthens inspiratory muscles (diaphragm, external intercostals, accessory muscles of neck) and expiratory muscles (internal intercostals, abdominals).
- Improves movement of the hyolaryngeal complex.
- Generates improved airflow through vocal folds.
- Improves respiratory support for safe swallow function.
- Improves protective cough and assists in airway clearance.
- Promotes diaphragmatic breathing.
- Decreases shortness of breath.
- Improves blood flow to resting and exercising limbs.

CLINICAL BENEFITS

- Increased maximal inspiratory and expiratory pressure (P_Imax, P_Emax) [10]
- Reduction of dyspnea (BORG scale) [11]
- Increased exercise tolerance (6MWT) and improved posture control, reducing back pain [32]
- Increased peak inspiratory and expiratory flow (PIF, PEF) [5,13]
- Reduced systolic and diastolic blood pressure [19]
- Improved quantity and quality of sleep [19]
- Improved laryngeal function for speech and swallow [20,25]
- Improved reflex cough for better pulmonary hygiene [25]
- Improved diaphragmatic function, supporting breathing and speech [1,31]

ADDITIONAL BENEFITS

- Improved quality of life (QOL) [11]
- Reduced hospitalization and healthcare requirements [15]
- Reduced risk of death [12]



RECOMMENDED PROTOCOL:

NOTE – these are protocol recommendations based on clinical evidence for RMT. These should not replace clinical judgement by the therapist and still need to be tailored to each patient’s case, status, and preferences.

Please carefully read and follow the general guidelines for **GETTING STARTED** and **FIRST SESSION**, or watch the free online training lessons (<http://www.pnmedical.com/start>).

RMT target:

6 days a week. 2 sessions per day (mornings and evening). 2 sets of 10 breaths per session.

Intensity:

At least 50% of maximum effort. The correct setting should allow you to tolerate a set of 10 breaths with moderate effort. Note that the settings for inhalation and exhalation need to be determined and set independently.

If using a manometer, the correct setting is around 50-60% of maximum inspiratory/expiratory pressure (MIP/MEP). This roughly corresponds to #5-6 on The Breather Effort Scale.

Ongoing therapy:

After maintaining training at baseline for approximately 1 week, increase resistances. When resistance is increased, repetitions may decrease initially then gradually increase again throughout the week.

Documenting progress:

Keep an RMT diary to note number of reps and sessions, settings, and other comments. RMT using **The Breather** should be built into your daily routine. You can download the free training journal at pnmedical.com/start or download the free Breather Coach app to track sessions.

See Section 7: Maintaining Respiratory Muscle Strength, for further details.



VII. MAINTAINING RESPIRATORY MUSCLE STRENGTH

As with peripheral muscle strength, respiratory muscles require exercise to maintain muscle strength. To maintain benefits achieved during initial training, RMT should be included into the daily routine. Scientific evidence has shown that respiratory parameters and exercise capacity continue to improve at least throughout the first year of RMT, but also that improvements are lost after discontinuation [9].

- For the optimal benefit of RMT, the patient should work towards completing 2 sets of 10 repetitions twice a day, 6 days a week.
- After maintaining training at baseline for approximately 1 week, increase resistances.
- When resistance is increased, repetitions may decrease initially then gradually increase again throughout the week.
- Choose the settings on the inspiratory and expiratory dials that allow the target number of reps per session without causing fatigue.
- Encourage building a set routine for using **The Breather**, such as after getting up and before going to bed, to optimize adherence.
- Begin training the patient (or caregiver) to monitor resistance & duration (reps) tolerance as soon as possible. The patient can develop these self-monitoring skills under the guidance of the therapist, therefore, increasing the likelihood of continuance of RMT after therapy sessions are completed. Include watching and feeling for correct technique as outlined above in the 'First Session' as well as monitoring for diaphragmatic breathing. In an effort to avoid RMT abandonment, educate patient to find their new (often lower) settings after illness, etc..
- Document patient progress, e.g. levels of resistance, reps & sets, numbers of sessions, Maximum Phonation Time, Ventilatory Response Index, Dyspnea Scale.
- If possible and useful, set patient targets, such as being able to walk up stairs without rest, etc.
- If patient often experiences shortness of breath or a 'panicking feeling', instruct them to simply breathe easily through **The Breather** at the lowest setting (not forcefully as in training). Expiratory resistance mimics pursed lip breathing and slower breathing inhalation is calming. Often it only takes a moment for breathing to become under control.



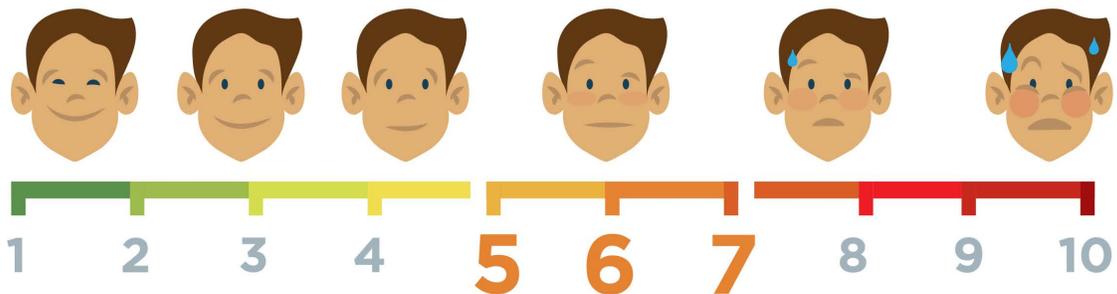
VIII. EFFORT SCALE

This effort scale is for therapist and patient use. It provides a guideline to meet the correct RMT intensity for optimal training benefit.

NOTE – This effort scale should not replace clinical therapist judgement.

THE BREATHER EFFORT SCALE

RATE YOUR EFFORT



TALK TEST

converse normally, normal breathing

converse normally, normal breathing

able to converse, light breathing

able to converse, moderate breathing

—IN THE ZONE—

able to converse, heavy breathing

able to speak 1-2 sentences, heavy breathing

broken sentences, heavy breathing

able to speak in syllables, very heavy breathing

unable to speak, very heavy breathing

cannot speak, gasping for breath



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