

User Manual



AN ACPLUS™ INTERCONNECTED TECHNOLOGY

MNL-0006 (4)



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Introduction / Welcome to OmniFlow™

The OmniFlow™ Breathing Therapy Biofeedback System is used for patients who have difficulty breathing. The device provides interactive breathing exercises using visual and

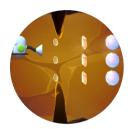
auditory biofeedback in a virtual experience that helps drive the desired breathing response to address the patient's underlying impairments/client factors. Exercise visualizations support inhalation, exhalation, breathing pattern, and airway clearance training.

Research supports the use of "virtual reality" augmented biofeedback in conjunction with traditional respiratory therapy techniques. Research demonstrates that improvement in function is dependent upon exercise intensity and the number of repetitions performed. The use of virtual reality in conjunction with traditional respiratory therapy techniques provides positive visual and auditory performance feedback, increasing patient engagement and improving clinical outcomes.



Introduction / Welcome to OmniFlow™

The OmniFlow[™] offers biofeedback-based exercise visualizations targeting all phases of breathing. The following breathing exercises are included with the OmniFlow[™]:



Diamond Mine

Deep inspiration, in order to improve inspiratory muscle power and inspiratory vital capacity.



Prehistoric Contest

Forced expiration, in order to improve expiratory muscle power.



Sail Away

Controlled expiration, in order to improve expiratory volume and flow.



Starry Road

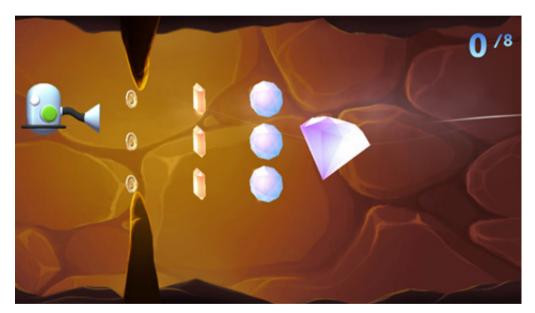
Rhythmical breathing, in order to normalize inhalation-exhalation ratio.



The Dandelion

Active cycles of breathing technique/Huff technique, in order to improve airway clearance by mobilizing and expelling secretions.

Diamond Mine: Deep inhalation

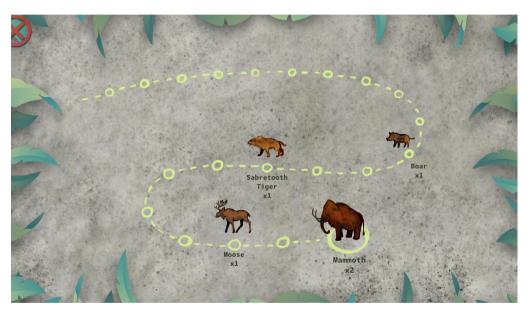


The goal of this exercise is to improve the patient's inspiratory muscle power and inspiratory vital capacity. As the patient attempts to breathe in a preset air volume in one breath, the inhalation is displayed as a vacuum cleaner collecting coins and jewels. A large diamond is collected for reaching the target volume.

The exercise has three preset levels of difficulty, as well as adjustable parameters (including minimum and maximum inspiratory flow target levels) to provide patient specific treatment and progression.

Deep inhalation exercise may facilitate improved diaphragmatic breathing and improved lung elasticity/volume, which leads to increased muscle endurance required to perform proper function, self-care, respiratory-swallowing coordination, and sustained speech production of words/phrases.

Prehistoric Contest: Forced expiration



The goal of this exercise is to improve the patient's expiratory muscle power.

As the patient attempts to breathe out a preset air volume in one breath, the exhalation is displayed as a prehistoric javelin being thrown. The more forceful the exhalation, the farther the javelin travels, and the larger the size of the prehistoric animal prize rewarded. If the preset target value is exceeded, a mammoth is the reward.

The exercise has three preset levels of difficulty, as well as adjustable parameters (including minimum and maximum expiratory flow target levels) to provide patient specific treatment and progression.

Forced expiration exercise helps in the preparation for functional forced expiration actions such as airway protection during swallowing, coughing or clearing the airway, and execution of adequate intensity/loudness during phonation.

Sail Away Exercise Introduction



The goal of the exercise is to control one's expiratory volume and flow. The patient is represented by a cloud and moves a sailboat to the next destination by breathing out. The patient must hereby control the expiratory flow and volume, based on the targets that have been set in advance by the therapist. During the exercise it is possible to develop a normal expiratory phase of breathing which can have a calming effect on the patient.

The exercise has three preset levels of difficulty, as well adjustable parameters (including target volume and maximum expiratory flow target levels) to provide patient specific treatment and progression.

Controlled expiration can help expel carbon dioxide and reduce dyspnea. It can improve eccentric control of the diaphragm to slow the pace of breathing and also retrain sustained phonation, voice intensity, and speech intelligibility.

Starry Road: Rhythmical Breathing



The goal of this exercise is to focus on rhythmical inspiratory and expiratory breathing. The patient attempts to match his/her inhalation to the rise and fall of the starry pathway (% conformity). During the exercise, the figure moves with every breath along the path and collects stars. The path height is determined by the preset volume; the path slope is determined by the preset duration.

The exercise has three preset levels of difficulty, as well adjustable parameters (including target volume and inspiration/expiration duration) to provide patient specific treatment and progression.

Proper breathing rhythm can help normalize the inhalationexhalation ratio, including for people with irregular breathing from pain, anxiety or stress. It can also improve respiratory pattern needed to retrain respiration-swallow cycle, sustained phonation, voice intensity, speech intelligibility.

The Dandelion Exercise Introduction



The goal of this exercise is to teach and perform the Active Cycle of Breathing Technique (ACBT)/Huff technique to mobilize and expel secretions without a high energy burden. The technique combines breathing control and lateral thoracic expansion, followed by proper huff technique. The patient's breathing moves the dandelion. As the patient attempts to control breathing, the dandelion sways gently. As the patient performs thoracic expansion, the dandelion sways with increased excursion. As the patient huffs, the dandelion seeds are blown into the air. The patient must perform an accurate huff technique to remove all the seeds. Screen instructions direct the patient through each phase.

The exercise has three preset levels of difficulty, as well adjustable parameters (including minimum expiratory flow target levels and inspiratory hold) to provide patient specific treatment and progression.

The ACBT/Huff technique promotes airway clearance of secretions. It can increase inspiratory/expiratory volume and flow to improve aerobic capacity/muscle endurance required to perform proper function and self-care and respiratory-swallow coordination.

Exercise Termination Criteria

Patients should be continuously monitored throughout the exercise session for the following clinical indicators.

Chest pain	Severe shortness of breath	Significant blood pressure changes
BP > 200/110 mmHg	Lightheadedness; BP drops > 20 mmHg	Oxygen saturation < 90%
Severe headache	Sudden onset of numbness or weakness	Onset of confusion
Ataxia	Pallor	Cyanosis
Cold and clammy skin	Noticeable changes in heart rhythm	Patient request to stop

Examples of Clinical Use

Breathing exercises are commonly incorporated into a patient's rehabilitation plan of care for the following:

- Dyspnea
- Abnormal breathing rhythm
- Pulmonary hyperinflation
- Diminished vital capacity
- · Reduced airway clearance
- Muscle weakness (e.g., postmechanical ventilation in ICU)
- Speech dysfunction
- Impaired phonation/voicing
- · Dysphagia/swallowing difficulty
- Autonomic nervous system (ANS) dysregulation (e.g., Pain, UI)
- · Decrease core stability
- Energy conservation training

Dyspnea

Dyspnea is shortness of breath, which can originate from multiple causes including lung disease, heart disease, or incorrect breathing technique. When dyspnea is caused by lung disease it could be due to decreased muscle power of the respiratory muscles. Training to facilitate inspiratory muscle function (strength, power and endurance) can increase the amount of air inhaled, which may improve oxygen perfusion and helps "regain breath" after exertion or improve activity tolerance.

Abnormal breathing rhythm

Abnormal breathing rhythm or an impaired inspiration/ expiration relationship (e.g. coordination and/or timing). Some examples of irregular breathing patterns include: tachypnea (rapid, and shallow breathing), apical breathing (upper chest breathing), hyperventilation, etc. The inspiratory and expiratory muscles can be trained specifically, or their coordination can be trained together to re-establish correct breathing. Training to normalize the inhalation-exhalation ratio, including for people with irregular breathing from pain, anxiety or stress. It also improves respiratory pattern needed to retrain respiration-swallow cycle, sustained phonation, voice intensity, and speech intelligibility.

Pulmonary hyperinflation

Pulmonary hyperinflation occurs when air gets trapped in the lungs, producing an increase in residual volume. Training to improve expiratory muscle function (strength, power and endurance) and breathing pattern may increase the amount of air being exhaled, which reduces carbon dioxide retention and dead airspace.

Diminished vital capacity

Helps train respiratory system to expand volumes and increase effective ventilation and oxygenation.

Reduced airway clearance

Helps train respiratory muscles to improve one's ability to separate, loosen and expel mucus.

Muscle weakness (e.g., post-mechanical ventilation in ICU) Immobility leading from bed rest, isolation or mechanical ventilation leads to general muscle weakness which requires require respiratory training of the inspiratory and expiratory muscle function for associated muscle disuse atrophy.

Examples of Clinical Use continued

Breathing exercises are commonly incorporated into a patient's rehabilitation plan of care for the following:

- Dyspnea
- Abnormal breathing rhythm
- Pulmonary hyperinflation
- Diminished vital capacity
- · Reduced airway clearance
- Muscle weakness (e.g., postmechanical ventilation in ICU)
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Speech dysfunction

Adequate duration of inspiratory and expiratory breathing is critical for proper articulation and rate of speech production.

Impaired phonation / voicing

Adequate volume of inspiratory and expiratory breathing is needed for production of appropriate vocal intensity, loudness, and resonance during voicing.

Dysphagia / swallowing difficulty

Adequate coordination and volume of inspiratory and expiratory airflow is crucial for execution of normalized respiration-swallow cycles, providing airway protection during swallow and in cough production.

Autonomic nervous system (ANS) dysregulation (e.g., Pain, UI)

The Autonomic nervous system (ANS) regulates involuntary physiological processes including HR, BP, RR. Slow deep or rthymical breathing can activate the vagus nerve of the parasympathetic nervous system, which produces the body's relaxation response and may decrease stress or pain.

Decrease core stability

The diaphragm plays a role in both breathing (e.g. lung capacity) and core stability including pelvic floor function and stability.

Energy conservation training

Proper breathing, rest and activity management may minimize muscle fatigue, joint stress, and pain.

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OmniFlow[™] Components and Essentials / System Components

Laptop and Accessories

OmniFlow[™] User Manual





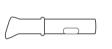
Power Adapter





Bluetooth® Mouse

Carry Case







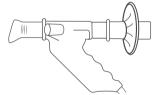
Airflow Sensor



Filter Connector



Inline Filter



Airflow sensor assembly

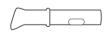
Airflow sensor

Airflow sensor is connected to an open USB port in the OmniME laptop.

The disposable bacterial viral filter

Disposable bacterial viral filter should be compatible with the airflow sensor being used. Optional inline filter and connector add an additional level of protection as needed.

Reorder Supplies 800.350.1100



P/N 20501

Spirette Disposable **Bacterial Viral Filter**

· Sold individually or in packages of 10



P/N 20301

Spirette Inline **Filter Connector**

· Sold individually or in packages of 10



P/N 20912

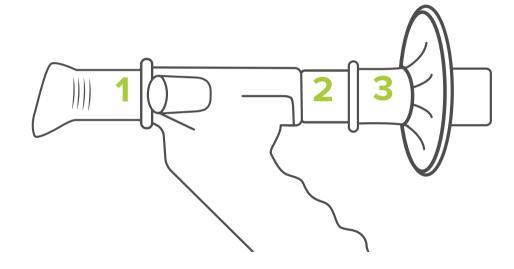
Spirette Inline Filter

· Sold individually or in packages of 10

Inline Filter Connector Setup

How to connect the optional inline filter to the OmniFlow™ airflow sensor

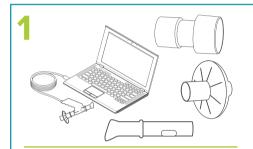
- 1 Insert the Spirette into the OmniFlow™ airflow sensor by aligning the Spirette triangle with the sensor triangle.
- 2 Attach the inline filter connector to the back of the spirette.
- 3 Attach the inline filter to the connector.





General Setup Guidelines

Turning the system ON



- Properly clean the airflow sensor and have a disposable bacterial viral filter available for patient use.
- Connect the airflow sensor to the USB connection on the side of the laptop.

2



• Power ON the laptop computer by pressing the on/off button.



• First time only: select the sensor to be used with the system.



- The main menu appears.
- Confirm the airflow sensor is connected by observing the airflow sensor connection icon in the lower right of the screen.

General Setup Guidelines

Turning the system OFF

1

☐→ Sign out 05082020-777

• Sign out the patient using the icon in the upper right corner.



• Shut down the system using the icon in the lower left.



- Disconnect the airflow sensor from the laptop.
- Properly dispose of the used airflow sensor bacterial vial filter.
- Clean and disinfect the airflow sensor.
- Place the airflow sensor in its storage bag.



• Place the laptop and its accessories back in the carry case.

Airflow Sensor

Airflow sensor used in exercise

- The airflow sensor measures the air moving through the tube.
- The airflow sensor is an instrument for engaging a patient in breathing exercises as part of their physical rehabilitation.
- The inspiratory and expiratory levels can be used to set thresholds for exercise, as well as assess exercise progression and outcomes.

The disposable bacterial viral filters

- To ensure hygienic use, the bacterial viral filter is disposable for single-patient, one time use.
- The bacterial viral filter is designed to work accurately with the airflow sensor and the OmniFlow™ software.
- Only use the bacterial viral filters recommended for use with the OmniFlow™ system.
- Do not use bacterial viral filter a second time. This symbol indicates that a bacterial viral filter can only be used by one patient and must be disposed after use. Use gloves when touching the filter to avoid contamination. Notice the expiration date of the filters. These can be found on the box and packaging of the filters.
- The optional inline filter provides additional protection for those who may wish
 to include a second filter, in order to keep the ambient environment clean for
 clinicians and patients. The inline filter ensures dependable "double protection"
 from infection.

Bacterial viral filter infection control

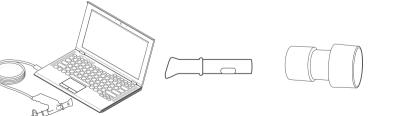
Avoiding contamination while using the OmniFlow

When handling the bacterial viral filter, you must be careful not to contaminate the next Spirette or $OmniFlow^{m}$ airflow sensor.

The *Spirette* is hygienically wrapped for single-patient use only. You must use a new *Spirette* for each patient.

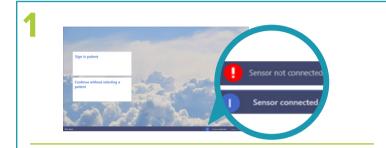
Bacterial viral filter handling guidelines:

- 1. Always wear disposable gloves.
- 2. Never touch the *Spirette* directly, but partly unwrap the wrapper and grip the *Spirette* with the wrapper still around the mouthpiece.
- 3. Keep the wrapper to the side while the patient is performing their breathing exercises.
- 4. After the patient has completed the breathing exercises, grip the *Spirette* together with the wrapper and dispose of properly (e.g., red bag).

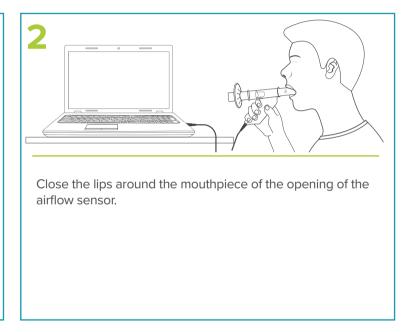




Airflow Sensor Connection and Use



Confirm the airflow sensor is connected by checking the icon status on the home page of OmniFlow™ software.

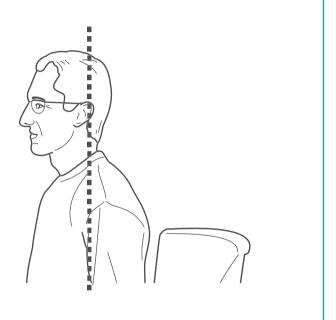


Preparing the Patient for OmniFlow™ Exercise

Patient set up and positioning

- Therapist should explain procedure and demonstrate proper technique prior to activity.
- Use a chair with arms in case the patient becomes lightheaded or faints.
- · Patient should:
- Wear loose fitting clothing (loosen any tight clothing to allow for full chest excursion).
- Sit upright with feet flat on floor.
- Avoid forward head posture (as that reduces vital capacity).
- Make a tight seal around mouth piece of airflow sensor.

Note: Dentures normally left in to help the patient hold mouthpiece in place.



Preparing the Patient for OmniFlow™ Exercise

Exercise instructions

Verbal instructions during OmniFlow™ exercise

Introduction

- Airflow sensor orientation "This introduction mode is to help you learn how to use the airflow sensor during breathing. Breathe in and out."
- Pre-exercise warm up "This introduction mode is to familiarize you to the exercise technique, and it also generates treatment levels."
 - "Breathe in deeply and fully." (hold for less than 2 seconds).
 - "Breathe out as hard and as fast until no more air can be expelled, while maintaining an upright posture."
 - Once all the air is expelled out of the lungs, "breathe in deeply and fully."

Deep inhalation – "This is exercise is for getting more air into your lungs. *Breathe in slow and steady.*"

Forced expiration – "This exercise is for getting air out of your lungs quickly. *Take a deep breath and exhale as hard and fast as you can.*"

Controlled expiration – "This exercise is for getting more air out of your lungs. *Inhale through the nose, and exhale slow and steady through the mouth until lungs are emptied."*

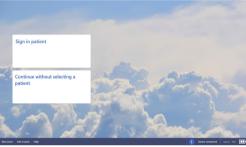
Rhythmical breathing – "This exercise is to normalize breathing rhythm. "Breathe out to make the figure float down; breathe in to make the figure float up."

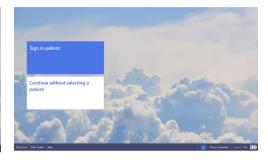
ACBT/Huff Technique – "This exercise is to help clear your lungs of mucus."

- "Breathe in and out normally to make the dandelion sway gently."
- "Breathe in deeply and hold."
- "Breathe out forcefully and continuously through your mouth, while keeping your airway open."

Module Selection and Home Screen







Module Selection

Select an option to launch a module.

Home screen orientation

- Shut down
 To power down the laptop.
- Exit Module
 To return to module selection screen (exit OmniFlow™).
- Help www.acplus.com/omniflow
- Airflow sensor connection

 Connection status of the airflow sensor.
- % Battery charge remaining
 Percentage level of laptop battery power.

• Sign in patient

- Start a treatment for a new or existing patient. Signing in with a password is necessary.
- Continue without selecting a patient Directly start an exercise without signing in a patient or therapist.

Sign in Patient







Sign in patient

The clinician is prompted to enter the "Therapist Code" to access the patient database.

Access code – 2823

Patient overview

- **Search patient** Select a patient to start a new session.
- Start session
- Add a new patient
- Manage patient
- Discharge a patient
- **Discharged patients** Access previously discharged patients.

Note: Select Start button at top left corner to get back to Home screen.

Add patient

- Patient ID Enter a patient identification. For privacy, do not use patient's name.
- Comments Comments can be added if needed.
- Cancel New patient record will be removed.
- Create patient This will complete the Add patient process and advance to Patient dashboard screen.

Patient dashboard





New Patient dashboard

Existing Patient dashboard

Patient dashboard

After the "Create patient" button is selected, the system will advance to the Patient dashboard.

- Sign out Select icon at top right corner to sign patient out of a session.
- Create Exercise protocol/Exercise protocol Creates a single or series of exercises that are patient-specific.
- **Introduction** This selection has two modes, one to orient patient on how to properly use the airflow sensor during breathing and another to familiarize patient to the exercise technique.
- Start single exercise A single exercise can be started for the signed in patient.
- Manage patient Access to patient information.
- View patient history View patient exercise history.
- Last played exercise The system will recall the last exercise performed by the patient (existing patient only).

Create Exercise protocol





Patient dashboard

Create Exercise protocol –
 Select this option from the Patient dashboard to initiate protocol development.

Manage patient

- The Manage exercise protocol section of the screen will be blank, allowing clinician to add new exercises to the protocol.
- Add new exercise Select to add new exercise and advance to Choose exercise screen.

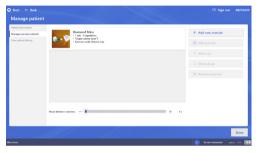
Note: Selecting the Start button at top left corner will bring you back to Patient dashboard.

Create Exercise protocol continued









Choose exercise

Select one of the four exercise types, and the screen will advance to the difficulty level selections.

 The Dandelion is not available as an exercise protocol selection, as it is not a time-based exercise.

Choose difficulty level

Select the exercise level of difficulty: Easy, Moderate, Hard or Customize.

Confirm parameters

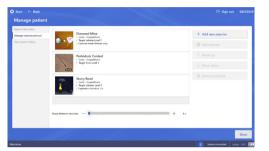
Exercise parameters are listed on the screen.

- Add to protocol
- Edit parameters
- Cancel the exercise

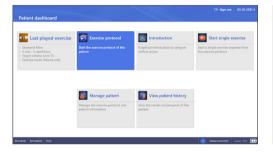
Manage Patient

- After the exercise has been added to the protocol it will be displayed on the Manage exercise protocol section of the Manage patient screen.
- Repeat the Add new exercise process to add additional exercises to the protocol.

Manage exercise protocol









After the protocol is created a dashboard of tools are available to edit the exercise, alter the position of the exercise, and remove an exercise.

- Pause between exercises Set rest time between exercises using sliding bar.
- **Done** When protocol is complete, select Done in bottom right corner.

Manage patient – Manage exercise protocol

- Add new exercise Continue to add new exercises within existing protocol.
- Edit exercise Edit exercise parameters within existing protocol.
- Move up/Move down Move exercises up or down to change the order of the exercises within existing protocol.
- Remove exercise The software will prompt the clinician to confirm the removal of the selected exercise.

Patient dashboard

• Exercise protocol – Select this option from the Patient dashboard to start existing exercise protocol.

Exercise protocol

After a protocol has been created, the exercise protocol screen provides access to Start or Edit the protocol.

Introduction









Patient dashboard

• **Introduction** – Select this option from the Patient dashboard.

Introduction Menu

This selection has two modes, one to orient patient on how to properly use the airflow sensor during breathing and another to familiarize patient to the exercise technique.

- Airflow sensor orientation
- Pre-exercise warm-up

Airflow sensor orientation

- Orients patient on how to properly use the airflow sensor during breathing.
- Displays a simple volume level over time trace.
- Expiration trace display line goes up.
- Inspiration trace display line goes down.

Pre-exercise warm-up

- Familiarizes patient to exercise technique.
- Repeat until 3 acceptable trials achieved.
- Generates suggested treatment levels (1-25) based on performance.
- X-axis = volume; Y-axis = flow
- Expiration Above x-axis
- Inspiration Below x-axis

Start single exercise









Patient dashboard

- Start single exercise Select this option from the Patient dashboad to start a single exercise.
- If "Continue without selecting a patient" is chosen from the home screen, it will advance to a choose exercise screen where Start exercise can be selected.

Choose exercise

- Diamond Mine Deep inhalation.
- Prehistoric Contest Forced expiration.
- Sail Away Controlled expiration.
- Starry Road Rhythmical breathing.
- The Dandelion ACBT/Huff Technique.

Choose difficulty level

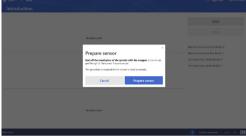
- Once exercise type is selected, second row appears on screen with difficulty level selections.
- All exercises have three preset difficulty levels (Easy, Moderate, Hard).
- All exercises can also be Customized (set exercise parameters to the patient's specific needs).

Confirm parameters

- Once exercise and difficulty level are chosen, options are to Start exercise or Edit parameters.
- Edit parameters Select this option to advance to Configure parameters screen with option to edit each parameter.
- Start exercise Select this option to start exercise. Clinician will be prompted to prepare sensor prior to exercise screen.

Start single exercise continued





Edit parameters

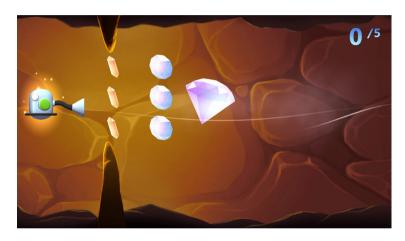
• Parameters available for editing depend on the exercise selected.

Prepare sensor

- Prior to starting any exercise, the sensor must be prepared by sealing both ends of the spirette so no air can get through.
- With both ends of the spirette covered, select "Prepare sensor" to continue to the exercise.

Operation of the OmniFlow[™] **Software**

Diamond Mine



Diamond Mine: Deep inhalation

The goal of this exercise is to improve the patient's inspiratory muscle power and inspiratory vital capacity. As the patient attempts to breathe in a preset air volume in one breath, the inhalation is displayed as a vacuum cleaner collecting coins and jewels. A large diamond is collected for reaching the target volume.

- A vacuum cleaner and several valuables including coins, jewels and a diamond appear on the screen. When the patient breathes in through the airflow sensor, the vacuum cleaner will collect the valuables.
- When the large diamond is collected, the patient gets a score of 100% for this repetition. After each repetition, the achieved score is shown as a percentage of the target volume.
- A stalactite appears from the cave ceiling to represent the minimum inspiratory flow threshold. A stalagmite appears from the floor to represent the maximum inspiratory flow threshold. This challenges the patient to control their flow between the target threshold values.
- The number of completed repetitions is shown in the upper right corner.
- To exit the exercise, select the red X in the upper left corner.

Diamond Mine continued



Exercise parameter settings

- **Sets/reps mode** Regular mode is based on sets with repetitions and Time mode is based on a maximum time duration for each set.
- Number of sets/reps The exercise is done in sets with a number of repetitions. The clinician can indicate a pause time between sets and a pause time between repetitions.
- Target flow level The target inspiratory flow level.

- Pause During the exercise, the clinician can override the pause time with a mouse click
- Target volume The target inspiratory volume level that the patient must inhale to reach the diamond.
- Exercise mode By default, the exercise is performed by breathing in a target inspiration volume level. It is possible to set a minimum flow level that must be exceeded by the patient. It is also possible to set a minimum and a maximum flow level threshold.



Diamond Mine completion screen

- At the end of the exercise, a brief transition screen will appear as the exercise results are tabulated.
- Once the results are tabulated, the completion screen will appear for approximately 15 seconds.
- Completion screen includes number of attempts, best try and average inspiratory target volume percentages.
- The system will then advance to the Outcomes screen.



Exercise Summary

- Best Inspiratory volume level The highest inspiratory volume level achieved per set is in green.
- Average inspiratory volume level –
 The average inspiratory volume level per set is in blue.
- Average of all repetitions –
 The orange line shows the average inspiratory volume level of all reps across sets.
- Exercise session date, time and duration are noted in the top right corner of the screen.

Diamond Mine continued









Outcomes per Repetition

- The outcomes per repetition show the result of each repetition. One row shows all repetitions of one set.
- For this exercise the inspiratory volume levels and peak inspiratory volume levels are shown.
- To see the results of additional sets, scroll down using touch screen or mouse.

Flow-Volume Loops

- The loops show the Flow level against the Volume level. Every graph shows one repetition. A row shows all repetitions from one set.
- The loops show negative values because only inspiration is measured for this exercise.
- The axes all have the same gradation so they can be easily compared with each other.

Parameters & Comments

- The Parameters section displays all of the exercise parameter settings with the performed exercise.
- The Comments section allows the clinician to add a comment about the session.
- Bottom right corner of any of the outcomes screens include a QR-code button, when selected a QR-code pop-up will appear.

End of Treatment: QR Code

• Select the QR code button from the bottom right corner of any outcomes screen, and a QR code with embedded device information, protocol parameters and outcomes results will appear. The QR code can be scanned in order for this information to be added to the patient's Electronic Medical Record using the ACPlus® application.

Operation of the OmniFlow[™] **Software**

Prehistoric Contest



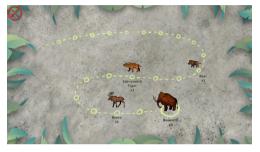
Prehistoric Contest: Forced expiration

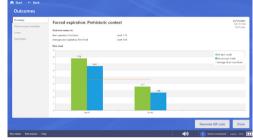
The goal of this exercise is to improve the patients expiratory muscle power.

- As the patient attempts to breathe out a preset air volume in one breath, the exhalation is displayed as a prehistoric javelin being thrown.
- The more forceful the exhalation, the farther the javelin travels, and the larger the size of the prehistoric animal prize rewarded.
- If the preset target value is exceeded, a large prehistoric mammoth is the reward.
- The first animal (squirrel) is rewarded if the patient's peak expiratory flow is anywhere from 0 to just below 25% of the target expiratory flow.
- All other animals are a linear mapping between 25 to 100% of the target expiratory flow.
- The last animal (mammoth) is rewarded if the patient's peak expiratory flow reaches or exceeds the target expiratory flow (≥ to 100% of target flow).

Prehistoric Contest









Exercise parameter settings

- Sets/reps mode Regular mode is based on sets with repetitions and Time mode is based on a maximum time duration for each set.
- Number of sets/reps The exercise is done in sets with a number of repetitions. The clinician can indicate a pause time between sets and a pause time between repetitions.
- Target flow level The target expiratory flow level.

Prehistoric Contest completion screen

- At the end of the exercise, a brief transition screen will appear while the results are being tabulated.
 The screen will display the names of each animal award and the number of times the award was provided.
- Once the results are tabulated, the completion screen will appear.
- The system will then advance to the Outcomes screen.

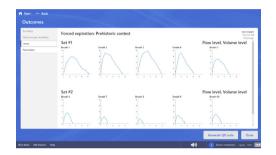
Exercise Summary

- Best expiratory flow level The highest expiratory flow level achieved per set is in green.
- Average peak expiratory flow level The average expiratory flow level per set is in blue.
- Average of all repetitions The orange line shows the average expiratory flow level of all reps across sets.
- Exercise session date, time and duration are noted in the top right corner of the screen.

Outcomes per Repetition

- The outcomes per repetition show the result of each repetition. One row shows all repetitions of one set.
- For this exercise the peak expiratory flow levels are shown.
- To see the results of additional sets, scroll down using touch screen or mouse.

Prehistoric Contest continued







Flow-Volume Loops

- The loops show the Flow level against the Volume level. Every graph shows one repetition. A row shows all repetitions from one set.
- The loops show positive values because only expiration is measured for this exercise.
- The axes all have the same gradation so they can be easily compared with each other.

Parameters & Comments

- The Parameters section displays all of the exercise parameter settings with the performed exercise.
- The Comments section allows the clinician to add a comment about the session.
- Bottom right corner of any of the outcomes screens include a QR-code button, when selected a QR-code pop-up will appear

End of Treatment: QR Code

• Select the QR code button from the bottom right corner of any outcomes screen, and a QR code with embedded device information, protocol parameters and outcomes results will appear. The QR code can be scanned in order for this information to be added to the patient's Electronic Medical Record using the ACPlus® application.

Sail Away



Sail Away: Controlled expiration

The goal of the exercise is to control one's expiratory volume and flow. The patient is represented by a cloud and moves a sailboat to the next destination by breathing out. The patient must hereby control the expiratory flow and volume, based on the targets that have been set in advance by the therapist. During the exercise it is possible to develop a normal expiratory phase of breathing which can have a calming effect on the patient.

- When the patient exhales, the sailboat will be blown forward toward an island.
 Controlling the expiratory flow and volume allows for the boat to sail to its destination.
- During each repetition, buoys will appear when the patient reaches 25% and 75% of the target volume. When the patient reaches 100% of the target volume, the boat arrives at an island with a black and white checkered 'Finish' flag.

There are two ways in which the exercise may not be performed correctly and therefore the goal is not achieved:

- If the patient does not exhale enough air to reach the target volume, the boat will only land on a plain rock, instead of the grassy island.
- If the patient exhales too forcefully, the sail of the boat will break. A visual aid bar directly below the cloud is green when there is appropriate expiratory flow, but turns red as the patient reaches maximum flow level. When this bar threshold is exceeded, a red triangle warning sign appears and then the sail breaks.

Sail Away continued



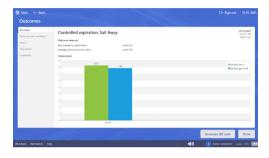


Exercise parameter settings

- **Number of sets/reps** The exercise is done in sets with a number of repetitions.
- Time between repetitions –
 The clinician can indicate a pause time between repetitions.
- Target volume level The target expiratory volume level that the patient must exhale to reach the grassy island.
- Maximum Expiratory flow threshold The maximum expiratory flow threshold value.

Sail Away completion screen

- At the end of the exercise, a brief transition screen will appear as the exercise results are tabulated.
- Once the results are tabulated, the completion screen will appear.
- Completion screen includes number of attempts, number of times the goal was reached (target expiratory volume without exceeding the maximum expiratory flow), average target expiratory volume percentage, number of times target expiratory volume was not reached, number of times maximum expiratory flow was exceeded.
- To advance to the Outcomes screen, click the red X in the upper left corner of completion screen.

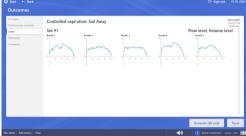


Exercise Summary

- Best expiratory volume level The highest expiratory volume level achieved per set is in green.
- Average expiratory volume level –
 The average expiratory volume level per set is in blue.
- The orange line is the average expiratory volume of all reps across sets.
- Exercise session date, time and duration are noted in the top right corner of the screen.

Sail Away continued









Outcomes per Repetition

- The outcomes per repetition show the result of each repetition. One row shows all repetitions of one set.
- For this exercise the expiratory volume levels and average expiratory flow levels are shown.
- To see the results of additional sets, the clinician scrolls down using touch screen or mouse.

Flow-Volume Loops

- The loops show the Flow level against the Volume level. Every graph shows one repetition. A row shows all repetitions from one set.
- The loops show positive values because only expiration is measured for this exercise.
- The axes all have the same gradation so they can be easily compared with each other.

Parameters & Comments

- The Parameters section displays all of the exercise parameter settings with the performed exercise.
- The Comments section allows the clinician to add a comment about the session.
- Bottom right corner of any of the outcomes screens include a QR-code button, when selected a QR-code pop-up will appear

End of Treatment: QR Code

• Select the QR code button from the bottom right corner of any outcomes screen, and a QR code with embedded device information, protocol parameters and outcomes results will appear. The QR code can be scanned in order for this information to be added to the patient's Electronic Medical Record using the ACPlus® application.

Starry Road



Starry Road: Rhythmical breathing

The goal of this exercise is to focus on rhythmical inspiratory and expiratory breathing. The patient attempts to match his/her inhalation to the rise and fall of the starry pathway (% conformity). During the exercise, the figure moves with every breath along the path and collects stars. The path height is determined by the preset volume; the path slope is determined by the preset duration.

- By breathing in and out, the patient can steer the figure up and down. When the figure stays within the path, the path will be filled with colors.
- The conformity percentage at the upper right corner indicates the amount of time that the path is followed correctly.



Starry Road continued



Exercise parameter settings

- Number of reps/sets
- · Time between sets
- Target volume
- Inspiration/Expiration duration
- Path width Wider path allows for increased ease of conformity. Narrow path increases difficulty to maintain conformity.
- Expiration only Allows for the exercise to be expiration only.

 If selected, the figure only moves on the upward part of the path. The figure will automatically drop to the bottom of the screen when the patient is not exhaling.
- Pause before each rep

 Adaptive Path – Conformity is how well the patient is able to keep the figure on the path during inspiration and expiration. Depending on the patient's performance, the slope of the starry path will automatically decrease or increase for the next exercise set.

Patient has difficulty keeping figure on the path (<60% conformity). To make it easier, the inspiration/expiration durations shorten (incrementally by 10% down to 60% of original value), which increases the slope of the path (i.e. steeper slope).

Patient is able to keep figure on the path (> 90% conformity). To make it harder, the inspiration/expiration durations lengthen (incrementally by 10% up to 120% of the original value), which decreases the slope of the path (i.e. gentler slope)

 Visual display – The starry road defaults to the figure moving down with expiration and up with inspiration. The visual display can be inverted to the figure moving up with expiration and down with inspiration.

Note: Starry Road is the only exercise visualization where parameters can be adjusted while in use. On the top center of the screen, select the "Parameters" tab for a drop down to adjust target volume, inspiration or expiration duration, and pause features.

Starry Road continued





Starry Road completion screen

- At the end of the exercise, a brief transition screen will appear as the exercise results are tabulated.
- Once the results are tabulated, the completion screen will appear for approximately 15 seconds.
- Completion screen includes number of attempts, best try and average conformity percentages.
- The system will then advance to the Outcomes screen.

Exercise Summary

• Maximum conformity (%) - The max conformity achieved per set is in green. For each set, the system measures how accurate the path is followed. If the patient stays on the path for the entire duration of the exercise, a percentage of 100% is achieved.

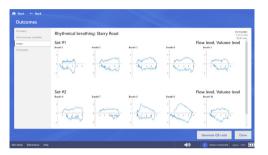
- Average conformity (%) The blue horizontal line represents the average result of all sets. If only one set is completed, the average and highest value will be the same and there will be no blue horizontal line
- · Exercise session date, time and **duration** are noted in the top right corner of the screen.



Outcomes per Repetition

- The outcomes per repetition show the result of each repetition. One row shows all repetitions of one set.
- For this exercise the expiratory volume levels and peak expiratory flow levels are shown.
- To see the results of additional sets. the clinician scrolls down using touch screen or mouse.

Starry Road continued







Flow-Volume Loops

- The loops show the Flow level against the Volume level. Every graph shows one repetition. A row shows all repetitions from one set.
- The axes all have the same gradation so they can be easily compared with each other.

Parameters & Comments

- The Parameters section displays all of the exercise parameter settings with the performed exercise.
- The Comments section allows the clinician to add a comment about the session.
- Bottom right corner of any of the outcomes screens include a QR-code button, when selected a QR-code pop-up will appear

End of Treatment: QR Code

• Select the QR code button from the bottom right corner of any outcomes screen, and a QR code with embedded device information, protocol parameters and outcomes results will appear. The QR code can be scanned in order for this information to be added to the patient's Electronic Medical Record using the ACPlus® application.

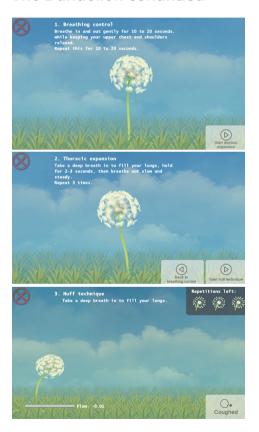
The Dandelion



The Dandelion: ACBT/Huff technique

The goal of this exercise is to teach and perform the Active Cycle of Breathing Technique (ACBT)/Huff technique to mobilize and expel secretions without a high energy burden. The technique combines breathing control and lateral thoracic expansion, followed by proper huff technique. The patient's breathing moves the dandelion. As the patient attempts to control breathing, the dandelion sways gently. As the patient performs thoracic expansion, the dandelion sways with increased excursion. As the patient huffs, the dandelion seeds are blown into the air. To remove all the seeds, the patient must demonstrate an accurate huff technique by exceeding the set expiratory threshold. Screen instructions direct the patient through each of the 3 phases of the exercise.

The Dandelion continued



The Dandelion: ACBT/Huff technique Phase 1: Breathing Control

Breathing control helps relax the airways.

- The patient breathes in and out gently at their own pace for 10–20 seconds, keeping their upper chest and shoulders relaxed. During this phase, the dandelion will gently sway back and forth.
- To advance to ACBT Phase 2, click or touch the 'Start thoracic expansion' button on the lower right corner of the screen.

Phase 2: Thoracic Expansion

Thoracic expansion helps get air behind the mucus to move it off the small airway walls.

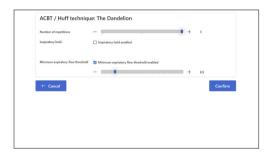
- The patient breathes in deeply to fill the upper chest and expand the ribcage outward, holds the breath for 2–3 seconds, then breathes out slow and steady. Repeat 3 times. During this phase, the dandelion will sway even further back and forth.
- To advance to ACBT phase 3, click or touch the 'Start huff technique' button on the lower right corner of the screen.
- To move back to ACBT phase 1, click or touch the 'Back to breathing control' button on the lower right corner of the screen.

Phase 3: Huff Technique

In Phase 3, huffing helps move the mucus into the large airways so it can be expelled from the lungs.

- The patient breathes in as deeply as possible, then exhales forcefully and continuously through the mouth, while keeping the airway open. Perform as many huffs as needed to expel mucus. During this phase, the dandelion seeds are blown away into the air with the force of the huff.
- When all the target repetitions are performed, the exercise will return to ACBT phase 1, Breathing Control.
- If the patient coughs while performing the huff, click or touch the 'Coughed' button on the lower right corner of the screen. This will return the exercise to ACBT Phase 1, Breathing Control.

The Dandelion continued









Exercise parameter settings

- Number of repetitions: The target number of huff repetitions for the exercise.
- Minimum Expiratory Flow Threshold:
 The lower limit of expiratory flow
 in order to perform the exercise
 successfully.
- Inspiratory Hold: When enabled, the clinician can choose the duration of the inspiratory hold.

The Dandelion completion screen

- The ACBT/Huff technique is not a timed exercise. At the completion Phase 3 Huffing (three repetitions), this transition screen briefly appears then proceeds to Phase 1 Breathing Control.
- To end the exercise and advance to the Outcomes screen, click the red X in the upper left corner of the screen.

Exercise Summary

- Best expiratory flow level:
 The highest expiratory flow level achieved.
- Average peak expiratory flow level:
 The average expiratory flow level of all repetitions.
- Exercise session date, time and duration are noted in the top right corner of the screen.

Outcomes per Repetition

- The outcomes per repetition show the result of each repetition. One row shows all repetitions.
- For this exercise the peak expiratory flow level and duration of each repetition are shown.

The Dandelion continued







Flow-Volume Loops

- The loops show the Flow level against the Volume level. Every graph shows one repetition. A row shows all repetitions from one set.
- The loops show positive values because only expiration is measured for this exercise.
- The axes all have the same gradation so they can be easily compared with each other.

Parameters

• The Parameters section displays all of the exercise parameter settings with the performed exercise.

End of Treatment: QR Code

• Select the QR code button from the bottom right corner of any outcomes screen, and a QR code with embedded device information, protocol parameters and outcomes results will appear. The QR code can be scanned in order for this information to be added to the patient's Electronic Medical Record using the ACPlus® application.

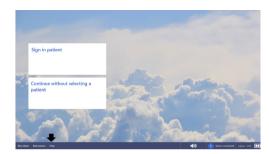
Patient information



View patient history



Embedded instructions





Manage patient - Patient information

• Patient's record can be updated or deleted.

Manage patient – View patient history

- Displays the exercises that have been performed by the patient.
- The screen shows the date, time, and name of each exercise.
- View Selecting this option at the bottom of the gray columns allows clinician to see the results and parameters of each individual exercise.

Help

- 'Help' icon is located on the bottom left toolbar throughout the software
- Select 'Help' to advance to Embedded Help Menu

Embedded exercise instruction selection

- Select to highlight the exercise to be reviewed
- Then, select 'Show topic'
- Each pop-up document provides a detailed review of the exercise
- To close the embedded instructions click on the white "X" in the upper right corner of the screen

Infection Control

Infection control equipment and principles of use

Definitions

Barrier Film – Intermediate-level disposable protective plastic film is designed to cover any surface that may be touched during a patient treatment, in order to help prevent cross-contamination. Barrier film is single-use only.

Germicidal Disposable Wipe – Low level and/or intermediate level disposable germicidal disinfectant wipe for use on OmniFlow™ system and accessories.

Universal Precautions

Universal Precautions must be implemented to prevent transmission from occupational exposure to bloodborne pathogens and other body fluids containing visible blood. Health care workers with exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment until the condition resolves.

Cleaning / Disinfecting of OmniFlow™

All OmniFlow™ equipment shall be cleaned and disinfected per facility infection control policy. ACP recommends the following guidelines:

Low-Level Disinfection

This is a recommended daily housekeeping practice to keep the equipment clean and free of contaminants which could contribute to transmission of infection. The following practices are recommended for use when treating intact skin without the presence of physiologic fluids such as blood, respiratory droplets, or urine:

 After each use, wipe common contact surfaces (e.g. keyboard cover, laptop, cart) with ACP germicidal wipes or facility approved equivalent, and allow to air dry.

- This technique will inactivate
 M. Tuberculosis as well as most bacteria
 and viruses. This will also facilitate
 removal of organic material contaminants
 from equipment.
- Disposable filters are for individual patient use only and are not be used on multiple patients.

Intermediate-Level Disinfection

The following practices are recommended for use when treating non-intact skin, or intact skin with the presence of physiological fluids such as blood, respiratory droplets, or urine:

- Perform low-level disinfection first.
- With a second ACP germicidal wipe, cover the surface and leave it wet for at least 5 minutes, and then allow to air dry.

Infection Control

Infection control equipment and principles of use continued

Intermediate-Level Procedure

Barrier film is designed to cover any surface that may be touched during a patient treatment and can be used in a variety of applications in order to help prevent cross-contamination. This procedure should be used when treating non-intact skin or intact skin with the presence of physiological fluids. Barrier film is for single-use only and should be discarded after each patient treatment.

Prior to treatment:

- 1. Wash hands and apply gloves.
- 2. Use low-level disinfection prior to barrier application.
- 3. Use keyboard cover or barrier film to fit over the operator surfaces.
- 4. Apply barrier sleeve over the USB cable of the airflow sensor.
- Prepare any items that clinician may come in contact with during treatment (e.g. airflow sensor, pens, assessment tools, cart handles).

After treatment:

- 6. With clean gloves, remove the barrier film and sleeve from the device components.
- 7. Use intermediate-level disinfection prior to the next treatment application.
- 8. Discard all disposables per facility medical waste policy.

Troubleshooting

Where to start?

Look up the issue the clinician is experiencing in the overview below. If the clinician's issue is not mentioned, or the clinician is not able to solve the problem, contact ACP Customer Support 1-800-350-1100 option 3.

Warning !

Do not make any changes to the hardware of the OmniFlow™ system yourself, other than the actions described here. ACP cannot guarantee the proper working of the OmniFlow™ after such hardware changes.

The computer does not turn on

If the clinician presses the power button, a back light on that button will light up. In addition, some sound of the internal fan will be audible. If these things do not happen, check the following:

- Is the power plug connected to main power?
- Is the power strip turned on?
- Is the power cable of the PC connected?

The screen does not display anything

The screen may be in Standby mode.

If there is no light on the power button of the screen at all, check the following:

- Is the power plug connected to mains power and is the battery of the laptop charged?
- Is the power strip turned on?
- Is the power cable of the PC connected?
- If the power cable for your OmniFlow™
 equipment appears damaged or frayed,
 please don't use it and contact our
 Customer Support department for a
 replacement.

The airflow sensor is not recognized

The airflow sensor must be connected to the USB-connection of the laptop. After about 10 seconds, the system will automatically connect to the system. The sensor-icon at the bottom right corner will be activated and indicate 'Sensor connected'.

If this has not happened after 30 seconds, try one of the following solutions:

- Connect the airflow sensor to another USB-connection in the laptop and wait for about 10 seconds. The system will automatically connect to the airflow sensor.
- Reboot the system with the airflow sensor connected.
- Make sure filter is aligned and fully inserted into the airflow sensor

If this does not solve the problem, contact ACP customer support 1-800-350-1100 option 3.

The sound does not work

Check the sound volume level of the system either by pressing the volume keys (F2 and F3) on the keyboard or by pressing the Windows icon key on the keyboard and typing "Sound" in the search feature. Also check to make sure the mute key (F1) on the keyboard is not activated.

Product Warranty

OmniFlow[™] Warranty

Standard Limited Product Warranty

The warranty information provided in this section is applicable only to products purchased from ACP, directly or through an authorized dealer. This section does not apply to leased products. The terms of maintenance and repair of any leased products are detailed in the separately executed agreement between the parties.

Warranty Coverage

This warranty provides coverage, for Equipment purchased, against manufacturer's defects in material and workmanship, and extends to the original owner of the product during the warranty period for that product. Only those items returned to the ACP Service Center within the warranty period, and also within thirty (30) days after notification to ACP of the defect, shall be eligible for repair under the Standard Limited Product Warranty. Buyer is responsible for shipping cost associated

with sending the Equipment to the ACP Service Center. ACP shall ship Equipment to Buver after repair at no cost to the Buyer provided repair is deemed to be under warranty. ACP may, at its discretion and only for valid warranty claim, repair or replace any part(s) that prove to be defective during the warranty period.

Warranty Exclusion Any and all warranty coverage will be void if any of the following have occurred:

- 1. The product contains repairs or replacement parts not furnished by ACP.
- 2. The product is damaged resulting from misuse or negligence.
- 3. The product has been tampered with and/or altered, including serial number alteration.
- 4. The product was used with accessories and/or supplies, including electrodes, not approved by ACP for use with the product.

Warranty Period

The following coverage is provided at no additional cost to the Buyer:

New Equipment / Product. Products purchased as new from ACP are warranted against manufacturer's defects in material and workmanship for a period of two (2) years from the date of purchase.

Refurbished Equipment / Product.

Products purchased specifically as Refurbished Equipment are warranted against manufacturer's defects in material and workmanship for a period of one (1) vear from the date of purchase.

Accessories. All accessories for ACP equipment / products are warranted against manufacturer's defects in material and workmanship for a period of three (3) months from the date of purchase.

Warranty Validation

The following information needs to be provided to the ACP Customer Service representative prior to the product being returned under warranty coverage:

- 1. Buyer name or account number as it appears under the "Bill TO" on the ACP or recognized ACP Dealer invoice.
- 2. Invoice Date and Number.
- 3. Model number, description, and serial number of equipment.
- 4. Detailed description of the problem.

OmniFlow™ User Manual

Product Warranty

OmniFlow™ Warranty continued

Return of Defective Equipment

Any Equipment returned to the ACP Service Center under warranty coverage must have the Warranty coverage validated and must receive authorization from ACP Customer Service prior to being received at the Service Center.

Shipping charges, insurance, and any other costs incurred in sending product to ACP Service Center is the responsibility of the customer and will not be refunded. ACP shall cover the shipping charges and related costs to return the unit to the customer, provided repair is deemed to be under warranty.

ACP is not responsible for any loss or damage to the Equipment prior to receipt at the ACP Service Center. Equipment returned for warranty service must be shipped complete with all accessories (except for manuals), in its original packing or equivalent so as not to be damaged while in transit.

NOTE: Any Equipment sent to the ACP Service Center that is not covered by the ACP Limited Product Warranty is subject to a minimum service and handling fee.

IMPORTANT: Do not ship the equipment to ACP Service Center without first securing authorization to do so. **Equipment sent in without authorization** from ACP Customer Service will not be accepted.



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800.350.1100 | acplus.com

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