



# OMNICYCLE<sup>®</sup> ELITE

## Motorized Therapeutic Exercise System

### User Manual

**Revised 12/08/2020**  
**Part No. 290A000533 Rev 9**

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## OMNICYCLE® ELITE

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### Symbols on the Product

Symbol	Used for	Symbol	Used for
	Serial number		Type B medical device
	Date of manufacture		Manufacturer
	Caution, consult accompanying documents		Caution, electrical precautions
	Consult instructions for use		CE mark of confidence
	Maximum extension of device base or supporting arm of upper body exerciser.	IP2X	Classification against water intrusion
	Proper disposal required. Do not dispose of with regular household waste. Follow state and/or local regulations.		Alternating current device.
	Observe the user manual	No symbol	Protection Class I
	Protect the product from humidity		Maximum body weight
	Danger due to movable parts		Do not step on covers or footrests

## WARNINGS & PRECAUTIONS

### Warnings

- Do not operate this device until the User Manual has been carefully read and is understood.
- Never operate the lower extremity exerciser with the pedals removed. Serious injury to the user or patient could result.
- Never select the start button until the appropriate upper or lower extremity icon selection has been confirmed. Serious injury to the user or patient could result when the default lower extremity is selected if the patient's legs are in front of the pedals.
- Never leave a resident or patient unattended while they are sitting at or actively using the Omnicycle® Elite.

### Precautions

- The Omnicycle® Elite should always be positioned so the patient's face is clearly visible by the therapist or operator to enable ongoing assessment of patient effort and exercise tolerance. The system should never be positioned in a way that the patient's condition/status cannot be appropriately monitored while using the system.
- Start with an initial exercise session of no longer than 15 minutes at a low load. Gradually increase the length and intensity of subsequent sessions to suit the patient's individual capabilities and load level.
- Caution should be used for patients with suspected or diagnosed cardio pulmonary conditions. Pay attention to heart rate limits and cardio pulmonary symptoms.
- Caution should be used in the presence of recent surgical procedures, fractures or healing bone and soft tissue when muscle contraction may disrupt the healing process. Ensure that Range of Motion (ROM), patient positioning, extremity and/or activity load limits are respected.
- Caution should be taken with any patient exhibiting psychological or physical hypersensitivity to the therapeutic treatment. Several attempts should be made to place them at ease so that their confidence and cooperation can be gained during the treatment.
- The Omnicycle® Elite is designed to be used in a sitting position only. Patients should never stand on the foot rests with the full weight of their body.
- The greater the distance between the Omnicycle® Elite and the patient's seat/wheelchair, the more the knee, hip and UE joints are extended. Start at a closer distance to avoid overextending the joints while providing the appropriate range of motion (ROM). This is particularly important when using the Omnicycle Elite® with patients recovering from fractures, total hip or knee replacement procedures, etc.
- In cases of partial paralysis, spasticity, instability or limited range of motion of the legs or arms, use the Omnicycle® Elite with the optional calf or arm supports. For the lower extremity (LE), adjust the pedal length/radius as needed. Consider using the Spasticity Management feature.
- If the Omnicycle® Elite is used by a patient in a wheelchair, use a wheelchair bracing/stabilizing device and the systems anti-tip protection straps to prevent accidental tip-over during exercise.
- Children must be constantly supervised when exercising on the Omnicycle® Elite. Never leave the Omnicycle® Elite unsupervised when children are present.
- If the Omnicycle® Elite is damaged, not operating normally, or producing abnormal noises or odors, stop the exercising session immediately, unplug the power cord and contact ACP Customer Service at 800-350-1100.
- A potential electric shock hazard exists once the device outer casing has been in part, or fully, removed. Only qualified service personnel should perform service and repairs. Warranty will be voided if the outer casing has been removed or tampered with.
- To avoid the risk of electrical shock, this equipment must only be connected to an electrical outlet with protective earth/ground. Only connect the Omnicycle® Elite to a properly grounded power outlet using a hospital grade cable.
- Caution should be used if disabling the microphone feature in the sonic stop application.
- Do not "PAUSE" the treatment to use the Omnicycle® Elite with another patient.

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## INDICATED USE

**The Omnicycle® Elite is a therapeutic exercise device and not a medical instrument for diagnostic purposes.**

**Please note that Accelerated Care Plus (ACP) cannot provide medical advice. If you have specific medical questions, please contact your healthcare professional.**

The Omnicycle® Elite is classified as powered exercise equipment intended for medical purposes, such as strengthening muscles, the restoration of motion to joints or for use as an adjunct treatment for obesity.

The Omnicycle® Elite can be used both as a lower body exerciser or an upper extremity exerciser. It is suitable for assisted exercise as well as active therapeutic exercise. It is intended for use in attended therapy.

- **Using the Omnicycle® Elite as a lower extremity exerciser:**

The patient sits on a stable chair or wheelchair. The Omnicycle® Elite is positioned on the floor in front of the patient. If possible the wheelchair footrests should be removed. The feet are fixed in the Omnicycle® Elite footrests and should be further secured by the Velcro® strap calf supports or foot retainer pads (optional feature). The Omnicycle® Elite is then started from the control panel on the display screen.

- **Using the Omnicycle® Elite as an upper extremity exerciser:**

The patient sits on a chair or wheel chair. The Omnicycle® Elite is positioned on the floor in front of the patient. The feet are placed into the pedals or on the wheelchair footrests. The upper extremity exerciser is adjusted to the correct height and reach. The arms are fixed to the exercising handles, armrests (optional feature) or Tetra-handles (optional feature). The Omnicycle® Elite is then started from the control panel.

**The Omnicycle® Elite is specifically recommended for persons with the following conditions:**

- Post stroke
- Multiple sclerosis
- Nerve injury
- Parkinson's Disease (especially upper extremity)
- Post-operative joint replacement Total Knee Arthroplasty (TKA), Total Hip Arthroplasty (THA), Shoulder, upper extremity (UE)
- Chronic Heart Failure (CHF)
- Chronic Obstructive Pulmonary Disease (COPD)
- Pneumonia
- Patients too weak or unbalanced to use a regular cycle
- Muscle disuse atrophy

The Omnicycle® Elite can be used as a biofeedback device to encourage greater patient participation, exercise effort, and/or exercise duration by varying pedal RPM, or right/left pedal force. Using these applications may facilitate cardiovascular, muscle, ROM, and/or cognitive exercise-related goals.

Three new biofeedback applications are available:

- **Soccer** - Pedaling faster or slower (RPMs) allows the patient to control the position of a goalie to prevent a soccer ball from going into the net. The RPMs required to position the goalie are pre-set ranges, in minimum, moderate, or maximum levels of difficulty. When the RPMs (patient effort) fall below the set parameter range, the goalie drops below the goal area. As the RPMs exceed the upper set parameter range, the goalie moves above the goal area. In the "assisted" exercise mode, the pedal RPMs are limited to 1-15 in minimum, 1-25 in moderate, and 1-35 in maximum. The set resistance level remains constant regardless of the pedaling speed.
- **Porcupine** - By varying the amount of force applied to the right and left pedals, the patient controls the position of a porcupine (right and left). The goal of the exercise is to position the porcupine under as many falling objects as possible (balloon, paper airplane etc.). Equal force on the right/left pedals holds the porcupine in the current position. The set resistance level remains constant regardless of the patient's pedaling speed.

- **Traffic Jam** - Varying the amount of force applied to the right and left pedals, the patient moves (“steers”) a car through traffic. The goal of the exercise is to drive the car without hitting and vehicles that appear along the way. Overtaking or passing vehicles requires even distribution of forces applied to the right and left pedals. An adjustable parameter called “Lane Preselection” enables the operator to select whether the vehicles to be avoided will appear on the right, left, the center lane, or randomly. By selecting the minimum level of difficulty, no other cars appear in adjacent lanes and the patient is simply required to keep the car positioned in the center lane. The set resistance level remains constant regardless of the pedaling speed.

## Biocompatibility

- All components and optional accessories of the Omnicycle® Elite, that the user might come in contact with when using the device as intended, are designed to meet the biocompatibility requirements of the applicable standards.

## Training Requirements

Staff who have gained their skills and expertise by means of professional medical training, professional experience, or by means of instruction/training by the manufacturer are deemed able to assess safety relevant regulations and recognize potential risks.

- Do not operate this device until the User Manual, has been carefully read and is understood.
- Before you start the Omnicycle® Elite exercise programs, consult the User Manual and understand the specific Warnings and Precautions related to the safe use of the device.
- Review and understand the section marked Operational Guidelines before operating the Omnicycle® Elite.
- Review and understand the proper use of the device controls and proper setup, features, and adjustment requirements of the Omnicycle® Elite.
- A member of your ACP team will install and configure the device before training. ACP will conduct a train-the-trainer style education process when the Omnicycle® Elite is delivered.
- During training:
  - Observe proper safety protocol by securing legs and arms sufficiently per user manual instructions
  - Start to exercise slowly
  - Increase to 70% of individual performance limit as you become more comfortable with the cycle
  - Avoid overstraining yourself

## Patient Requirements

Patients are persons who have been instructed by staff on the correct and safe use of the Omnicycle® Elite. The patient is responsible for the safe and correct use of the device.



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## THE OMNICYCLE® ELITE

### Delivery of the Omnicycle® Elite

Upon receipt of your Omnicycle® Elite, inspect the shipping container and contents for any obvious or concealed damage. All ACP products are packaged carefully for rapid, safe delivery. We guarantee delivery in perfect condition to the postal or delivery services. However any damage or loss incurred during transportation or delivery is the Postal or Delivery Company's responsibility. If damage or loss to the product and/or container is obvious or suspected, appropriate notation must be made on the signed freight bill at the time of delivery. All damage claims should be promptly filed with the delivering carrier and must be initiated by the addressee where the package was to be delivered. Retain the original shipping container and inserts for validation of damage claim for use at a later date.

Unpack and check all accessories. A list of enclosed accessories is provided with each unit to assist you in identification of the type and number of accessories.

### Transporting

The Omnicycle® Elite is equipped with wheels for ease of movement. However, the wheels are not suitable for moving the unit over uneven surfaces. The Omnicycle® Elite must be carried up or down stairs, which requires at least two persons. To move the unit, tip it and push it in front of you or pull it behind you. The strap on the front base of the cycle is for two person carry.

### Introduction

The Omnicycle® Elite is designed to be used for assisted therapeutic exercises (where the user's limbs are moved by the machine) and active therapeutic exercises (where the power is provided by the user). The system gradually transitions the patient from assisted exercise to more active exercise as the user gains power/mobility. The Omnicycle® Elite offers lower extremity exercise, as well as upper extremity exercise.

The Omnicycle® Elite biofeedback function/programs provide visual feedback to the patient reflecting lower extremity resistance or cadence. It is also used to indicate lower extremity right-to-left synergy and motor control. The system's biofeedback capabilities also assist in decreasing spasticity, or muscle spasms.

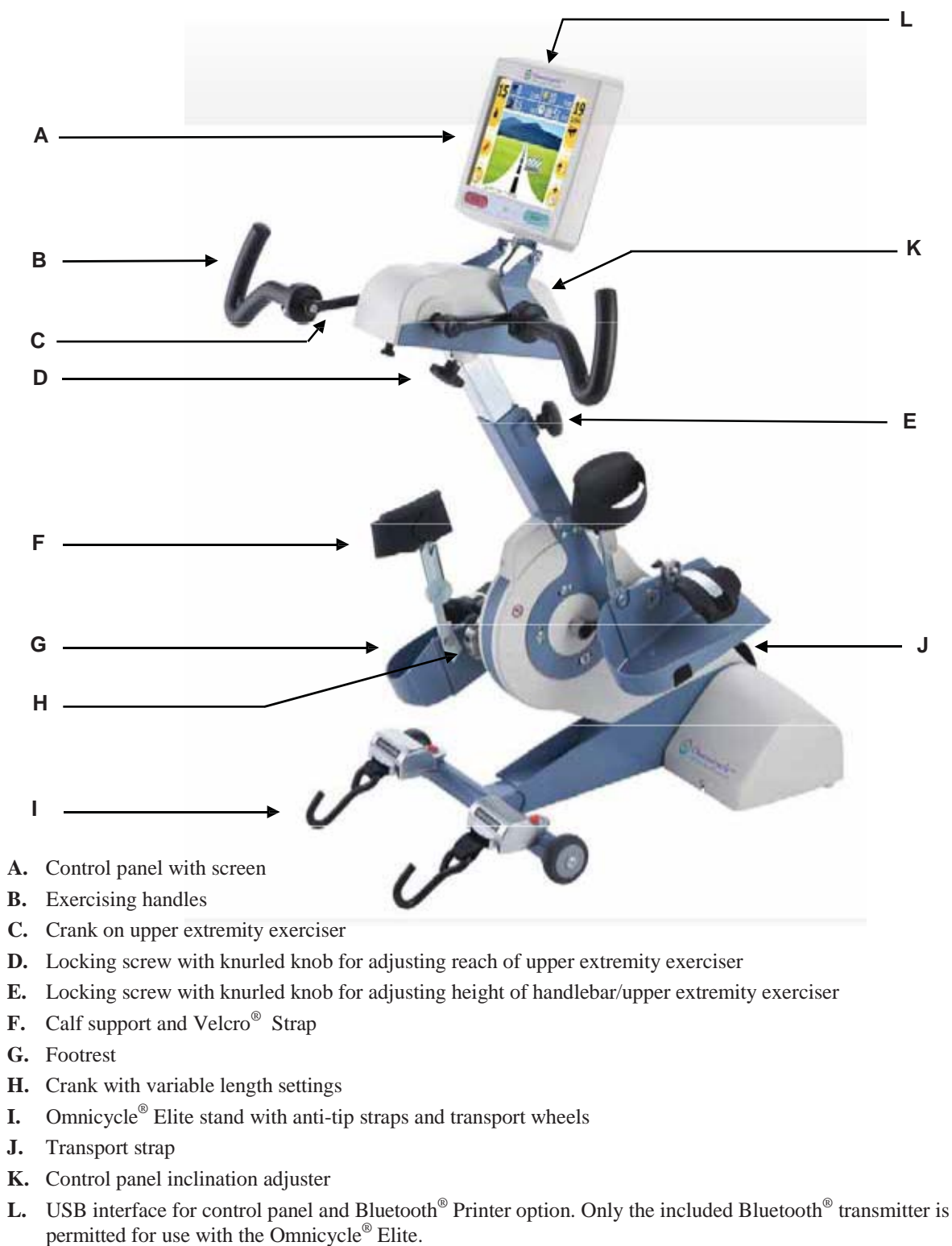
### Switching the Omnicycle® Elite On/Off

If the screen is **not** illuminated, the Omnicycle® Elite is in "STAND-BY" mode or "OFF." Press any button to switch the Omnicycle® Elite to normal operating mode. The screen will light up and, following a self-test lasting about 5 seconds the Omnicycle® Elite is ready for use. By pressing the green "START" button on the control pad, you can start the Omnicycle® Elite and begin exercising. Before starting the system, ensure that the patient is properly positioned, that their upper or lower limbs are appropriately attached to the arm/hand or footrest/calf supports and that there are no obstructions that may hinder the patient's motion. Pressing the "STOP" button on the control pad during an exercising session will "PAUSE" the exercise program. Pressing the button a second time ends the exercising session and the session analysis is displayed. Pressing and holding the "STOP" button (for at least 5 sec.) sets the Omnicycle® Elite to "STAND-BY" mode – the screen illumination switches off.

**NOTE:** Do not "PAUSE" the treatment to use the Omnicycle® Elite with another patient as the system will pick up where the previous exercise paused and produce the wrong Exercise Summary data.

**NOTE:** The purpose of this manual is to acquaint you with the Omnicycle® Elite operating features and functionality. Please read the manual carefully before attempting to operate the Omnicycle® Elite. If questions remain unanswered, contact your ACP sales representative, Clinical Program Consultant, or call ACP Customer Support at 800-350-1100. Outside the USA call 775-685-4000.

## Controls and Functions



## OPERATIONAL GUIDELINES

### Power Supply Operation

The Omnicycle® Elite is a line-power only device. Use only a 110 VAC wall outlet with a Hospital Grade power cord. Connect the Omnicycle® Elite to the power outlet socket using the provided power cord and position the cycle in such a way that it can be easily unplugged. In the event of an emergency, the Omnicycle® Elite should be unplugged from the wall outlet to prevent further injury. The Omnicycle® Elite is now ready for use. It can be started from the control panel.



### Basic Operational Sequence

When the cycle is in “STAND-BY” mode, the Omnicycle® Elite can be activated by pressing any button on the control panel. The screen will light up. During a self-test, which lasts about five (5) seconds, the welcome screen is displayed, followed by the system version screen. After the self-test, the unit will display the following start screen:

The Omnicycle® Elite is now ready for use. Pressing the “START” button at this point will start the exercise session with the basic default settings where the pedals are moving at a rate of 10 rpm in assisted exercise mode. When the patient pedals at a higher speed, the cycle will change to active exercise mode.



By pressing the “STOP” button once during the exercise session, the Omnicycle® Elite will “PAUSE”. It will resume the same session when the “START” button is pressed. If the “STOP” button is pressed twice, the exercise session will end, and the display will then show the “Exercise Summary” data, which can be printed out using the optional Omnicycle® Elite Bluetooth® Printer.

### Exercise Program Planning

The frequency and duration of exercise sessions on the Omnicycle® Elite should be individually planned and prescribed as appropriate for the patient’s condition. Proper patient-specific exercise dosing with the Omnicycle® Elite is extremely important if improvements in mobility, strength, endurance and neuromuscular reeducation, are to be achieved. It is recommended that relative to patient-specific needs and capabilities, therapeutic exercise sessions start at an easier intensity and shorter duration. As patients demonstrate good exercise tolerance, progressive increases in intensity and/or duration are recommended, dependent on each patient’s goals and clinical appropriateness. See the ACP Accelerated Clinical Practice Series; [Aerobic Exercise for Aging Adults](#) for specific exercise recommendations.

## Correct Posture

Always make sure that the patient's posture is optimized when exercising with the Omnicycle® Elite. The greater the distance between the Omnicycle® Elite and the patient's chair/wheelchair, the more the knee and hip or elbow and shoulder joints are stretched. This is particularly important in instances where the patient is recovering from fractures of the hip, or a recent total hip/total knee procedure has occurred. Therefore, you should start the exercise program with the Omnicycle® Elite positioned at the appropriate distance from the patient's chair/wheelchair to ensure comfortable range of motion.

## Active and Assisted Exercising

**“Assisted”** exercising means that the patient's limbs are moved by the Omnicycle® Elite without any effort on the part of the patient. The movement is provided by the Omnicycle® Elite's “motor-assist” capabilities. When first powered “ON”, the Omnicycle® Elite will always default to an assisted exercising phase with a preset resistance and speed. When the patient starts exercising more actively on their own with the same motion, the Omnicycle® Elite automatically transitions to more of an “active” exercising mode using less of the system's “motor-assist” function.

**“Active”** exercising means that the patient uses his/her own efforts and energy to turn the machine's cranks against a set resistance level. There are several different ways in which the patient can set up the machine for active exercising:

- **Set resistance:** the patient exercises against a set resistance level which does not change with speed.
- **Set power:** the patient works at a constant power output level (measured in watts). The resistance is automatically adjusted and stays constant at any pedaling speed. The resistance varies according to the pedal RPM.
- **Heart rate limit:** the patient exercises at a constant power until the heart rate limit is reached. If the patient's heart rate rises above the set limit, the resistance is automatically lowered.

## Muscle Hypertonia/Spasms

Muscle hypertonia can be effectively reduced by gentle and even movement on the Omnicycle® Elite. The distance between the Omnicycle® Elite and the patient's chair/wheelchair should be minimized to reduce spasticity. If this is combined with an upright sitting position and a short crank length, a reduction in the muscle hypertonia and spasticity can be observed within a short time. This effect may last for several hours past treatment.

The exercise program should be established so as to achieve the correct “degree” of hypertonia reduction. If a spasm occurs while exercising, the electronic circuitry of the Omnicycle® Elite detects it and immediately stops the motor – assuming the anti-spasm function has been activated (factory setting). The type of spasm suffered by most patients is an “extension spasm”. On occurrence of an extension spasm, the Omnicycle® Elite stops and then continues to rotate forward after a short delay. That forward rotation stretches the muscles and allows the spasm to recede. In the event of the less common type of spasm, the “flexion spasm,” the Omnicycle® Elite rotates backward after a spasm occurs.

## Cardio-Pulse Set

The Omnicycle® Elite has an embedded heart rate sensor that works with Polar® products (Cardio-Pulse set), which measures the heart rate accurately and can be used to track patient progress. Slightly moisten the inside of the chest band and strap it around the chest (close to the heart) so that the pads come in contact with the patient's skin, and the transmitter is facing towards the Omnicycle® Elite.

The supplied Polar® heart sensor uses a chest strap sensor that should be positioned on the patient's chest below the pectoral muscles. This is where the signal is the strongest. The type of ECG signal slightly varies from person to person. The ECG signal strength can depend on chest form, the anatomical location and position of the heart, position of the electrodes, and the amount of body fat.

A simple test can be performed to check that the heart rate sensor is functioning properly. The screen will show a blue heart symbol and a heart rate if the signals from the heart rate sensor are sufficiently strong and regular. If there is no heart rate signal, the heart symbol disappears. A weak/irregular heart rate signal is indicated by a red heart symbol.



At the beginning of the exercise, there is a learning process for the heart rate calculation. The pulse display needs some time to catch up with the actual pulse. This happens due to filtering in the software to filter out irregularities in the pulse rate. If the ECG signal is weak, the signal can get disturbed more easily. To ensure accurate detection (needed before measuring is possible) the contact between skin and electrodes needs to be constant.

To ensure good contact:

- Y Moisten the electrode areas of the heart rate sensor. At the beginning of the exercise session the skin may be dry and the moisture will help ensure better contact. When you start to sweat the contact will improve because the salt in the sweat conducts the electrical signals very well. If all else fails, the use of ultrasound gel is acceptable.
- Y Tighten the elastic strap. If the strap is loose, the movement of the electrodes will disturb ECG signal detection. If the standard-size strap does not fit satisfactorily, larger and smaller straps are available as accessories.
- Y Try different sensor positions to find the best for you. If the signal is weak when the sensor is placed right under the pectorals (recommended position), move the sensor left or right, lower or higher to find the best signal. There are known cases where heart rate is detected better when the sensor is turned upside down with the Polar logo facing out, or even when attached on the back. Find the best location for your individual patient.
- Y You may even need to shave a small area on the patient's chest. Hairy chests may weaken contact. If you cannot find the heart rate signal by positioning the sensor differently or with using conductive gel, shaving a small area for better conductivity may help.

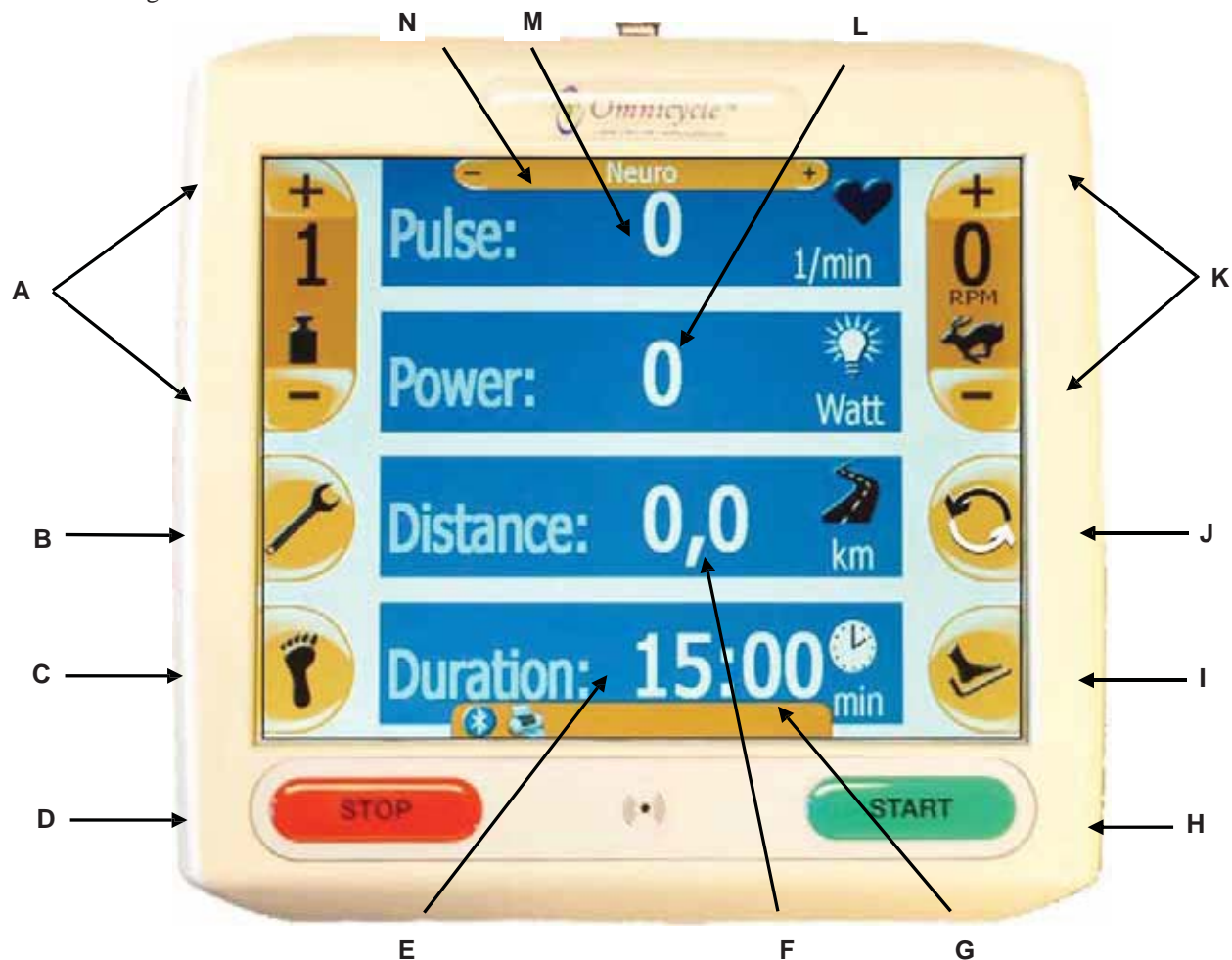
Chest strap cross-communications can happen when two patients with chest straps are too close to the same terminal simultaneously. The maximum transmission range between the heart rate sensor and the training computer is about 1 meter (3ft). Make sure you keep within this distance. If the distance gets further, the training computer may not receive all the heart rate signals from the heart rate sensor and, as a result, show the same heart rate for a long time. ACP may have provided your facility with a non-coded chest strap. These un-coded chest straps may be more susceptible to cross talk than the newer coded versions. The newer, coded versions can prevent cross-communications to a certain degree. Care should always be taken to keep patients and exercise equipment at greater than 1 meter intervals.

**NOTE:** *To prevent interference when several Omnicycle® Elite exercisers are being used with Cardio-Pulse sets, there should be a gap of at least 1 meter between exercisers.*



## Control Panel with Color Touch Screen

The color screen always shows all important settings and exercising session data. The basic start screen view shows the following information:



**A. Resistance level:** shows the exercise resistance level on a scale from 1 - 15 or the set power level from 0 – 80 watts. You can change the setting before or during the exercising session by pressing the + and – buttons. The following settings are possible:

- **Resistance (Neuro mode):** In “Neuro” exercising mode you can set the resistance level. The current resistance level is shown on a scale from 1 to 15. The maximum resistance depends on the preset motor power and has a maximum level of 22 Nm. The resistance can be increased by pressing the + (**plus**) button. To increase the resistance one increment at a time, press and release the button. The resistance can be reduced by pressing the – (**minus**) button and has a minimum setting of zero. If you press and hold the + or – button, the setting increases/decreases continuously up/down to the maximum/minimum. The set resistance remains constant at all speeds. A higher cadence means a higher power output.
- **Power setting in watts (Ortho/Cardio mode):** In “Ortho” and “Cardio” modes, exercising is based on a power output setting (up to a maximum of 80 watts). The power level is set by pressing the + or – button. The Omnicycle® Elite automatically modulates the resistance level according to the pedaling speed so that the set power is achieved.

**B. Settings:** The settings section is available before the start button has been pressed. This allows the user to change specific parameters within the Neuro, Ortho, and Cardio, Soccer, Porcupine, and Traffic Jam programs. The user may change settings like duration, difficulty level, spasticity, motor power, etc.

**Spasm detection function:** Once a program has started, the spasm detection function is active when the symbol turns to a lightning bolt, and is solid red. It is inactive if the symbol is white. The spasticity detection function on the Omnicycle® Elite protects spastic patients or those with sensitive bones or joints from undue stresses. Pressing the “Spasticity Detection” button toggles this function on or off (red or white). If the Omnicycle® Elite detects a muscle spasm, the system pauses immediately. The display indicates “SPASM”. After a pause of about 5 seconds, the machine continues at an assisted exercising speed 5 rpm lower than the previous setting. When in “Neuro” mode, the settings can be adjusted from to Fine, Medium or Rough.

- C. Lower extremity/upper extremity exercise selector:** The active option is shown. To change the setting as required before starting the training session press the icon to toggle between foot and hand (lower or upper exerciser). This is only possible if the upper extremity exerciser is activated on the cycle.
- D. Stop button:** Stops the exercising session. Pressing once pauses the exercising session. Pressing a second time ends the exercising session and displays the analysis for the last session.
- E. Remaining session time:** Displays the time remaining in the current exercise session.
- F. Distance completed:** Displays the distance (in km) for the current exercise session.
- G. Device bar:** Shows the user what additional devices are connected.
- H. Start button:** Starts the exercising session with an initial speed of 10 rpm and starts recording a new session analysis.
- I. Assisted entry:** The assisted entry function is used to move each pedal a position forward to makes it easier to properly secure the patient’s feet in the footrests/calf support. Activate/deactivate assisted entry mode by pressing the icon. If assisted entry mode is active, the symbol is red.
- J. Reset to default:** The user can select this button to return default settings for the current exercise. The default settings are stored under the system parameters section under the wrench icon. This icon is only available under the main menu, and then converts to the “Direction of rotation” icon once an exercise is started.

**Direction of rotation:** Change the setting during an exercising session by pressing the button next to the symbol. The current direction of rotation is indicated by the solid arrow. Pressing the button reverses the direction of rotation. A change of direction is always performed with a smooth transition. All other parameters (speed, motor power, UE/LE exerciser, spasticity detection) remain the same.
- K. Speed:** when exercising actively, this shows the actual speed of rotation of the cranks; when exercising in assisted mode, the preset speed is displayed, which is the speed of the motor. The speed can be increased by pressing the + button. To increase the speed one increment at a time, press and release the button. If you press and hold the + or – button, the speed increases/decreases continuously up/down to the maximum/zero. An exercising session always starts with a speed of 10 rpm. The maximum speed setting in assisted mode is 75 rpm.
- L. Power output:** Only shown when exercising actively; indicates power output in watts (Neuro mode) or energy consumption in kcal (Ortho mode).
- M. Heart rate:** Shows a heart rate and a green heart symbol if the heart rate sensor is connected and supplying a good heart rate signal. If the signals are weak, the heart symbol is red. If no heart rate sensor is connected, the heart symbol is grey.
- N. Program selection bar:** Allows the user to easily scroll between exercise programs.

## Cycle Setup, Features, and Adjustments

### Connecting the main power cord

Make sure that the plug is connected properly to the Omnicycle® Elite:

- Use only the power cord that is delivered with the device.
- The plug is designed to only fit one direction.
- Make sure that the power cord is properly seated.
- Once connected, the terminal display should turn on.

### Footrests

The footrests are designed for exercise with or without shoes. The feet should be securely fixed in the footrests with the Velcro® straps provided. To do so, pull the Velcro® strap over the top of the foot to the outer side of the footrest and press it against the Velcro® strip. Before every exercising session check that the patient's feet are correctly positioned in the footrests and are securely held by the Velcro® straps.

### Adjusting Crank Length, Adjustable Cranks

The Omnicycle® Elite has been fitted with adjustable cranks that can be lengthened or shortened. Thus the degree of movement can be adjusted individually to suit each patient's mobility and range of motion (ROM).

- Switch the Omnicycle® Elite "OFF" by pressing the "STOP" button
- Remove the foot from the footrest
- Undo the locking screw
- Slide the footrest along the crank to the desired position and firmly tighten the locking screw
- Adjust the opposite crank in the same way



Make sure that both cranks are set to the same length (the cranks are marked with a scale). In certain cases, it may be beneficial to have different crank lengths on each side (e.g. if the patient's legs are different lengths or have different degrees of mobility).

**NOTE:** *Never operate the lower extremity exerciser with the pedals removed. Serious injury to the user or patient could result.*

### Calf Supports

The calf supports help to secure the legs in cases of paralysis. They are connected to the footrests by a pivoting joint so as not to impair movement of the ankles.

- Adjust the height of the calf supports so that the cups fit around the calves. Secure the legs with the Velcro® straps.
- Make sure any loose fitting clothing is secured with the calf support Velcro® strap so it does not catch in the spinning assemblies during lower extremity exercise.
- When not using the calf support, loosen the two adjustment knobs on the calf support by turning counter clockwise and pull the support up and rotate forward through the angled slot. Fold the support bar forward and alongside the foot pedal bucket so it is out of the way of the patient during active exercise.

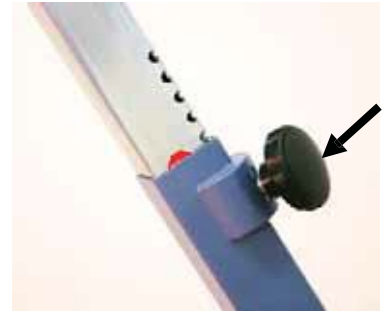
**NOTE:** *Patients who are secured to the Omnicycle® Elite by the Velcro® straps must always be supervised.*



## Adjusting Upper Extremity Exerciser Height

If you wish to exercise actively but suffer from muscle hypertonia or a lack of abdominal stability, the handlebar provides extra stability and balance. You can adjust the handlebar position to suit your individual size and sitting position.

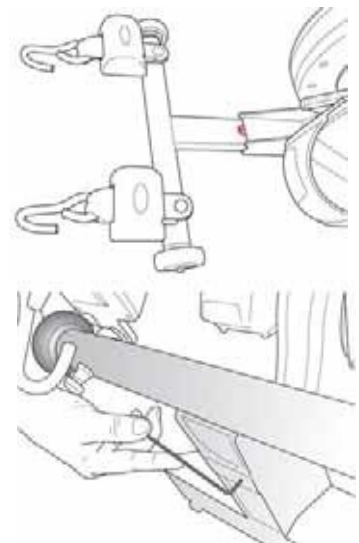
- Turn the knurled-knob counterclockwise unlocking the pull pin on the support tube. Pull the knob and hold while adjusting height.
- Adjust the handlebar to the desired height, release the knurled knob into the desired (height setting) hole and turn clockwise to retighten it. . Make sure that the handlebar support post is inserted to a depth of at least 4 inches in the support tube. The post has a line marking the minimum insertion depth.
- The handlebar position should be set at a height that positions the patient as upright as possible for optimal exercise motion.



## Adjusting the Omnicycle® Elite Stand

The Omnicycle® Elite is given greater stability by extending the “T” stand. This is especially important for upper extremity exercising.

- Tip the Omnicycle® Elite on its rear bottom edge.
- Undo the two fixing screws using the tool supplied.
- Extend the exerciser stand taking care not to exceed the maximum extension marked on the stand (5 inches).
- Retighten the fixing screws.
- Tip the Omnicycle® Elite forwards again into its normal position. To level the Omnicycle® Elite on an uneven floor, the rubber feet on the exerciser stand can be adjusted.
- Undo the lock-nut with an open-ended spanner (size 0.5 inches) and unscrew the rubber foot until the Omnicycle® Elite stands firmly.
- Retighten the lock-nut.



**NOTE:** When using the upper extremity exerciser, make sure that the Omnicycle® Elite stand is extended at least 4 inches.

## Adjusting the Upper Extremity Exerciser

The upper extremity exerciser for the Omnicycle® Elite can be adjusted to suit the size and sitting position of the patient. The upper extremity exerciser should be adjusted so as to obtain as upright an exercising position as possible.

### Adjusting the Reach

The ideal reach setting for the upper extremity exerciser is where the patients' arms are not quite fully extended when the Omnicycle® Elite handles are at their furthest position from the body.

- Undo the knurled-knob locking screw on the underneath of the upper extremity exerciser a small amount.
- Adjust the reach of the upper extremity exerciser as required.
- Retighten the knurled-knob locking screw.



## Adjusting Handles for Upper Extremity Exercise

The upper extremity exercise handles offer a variety of hand positions to accommodate various patient needs or limitations. The upper extremity exercise function should only be used if the patient is capable of securely gripping the handles. The exercise handles are easy to remove from the crank.

- To do so, press and hold the release button on the handle with your thumb and pull the handle off the shaft.
- Repeat the operation with the opposite handle.
- To refit the upper extremity exercise handle, press and hold the locating pin on the handle, and carefully slide it back onto the shaft on the crank until it clicks. The exercising handle should now be locked into position.

## Adjusting Handles for Lower Extremity Exercise

The Omnicycle® comes with a set of handles that allow the user to lock the upper extremity exerciser, and use these adapter handles as a support mechanism for the patient when performing lower extremity exercise. These handles convert the upper extremity exerciser into non-moving handlebars in a few simple steps.

- Lock the upper extremity cranks by turning the arrester knob a quarter turn and then let go
- Turn the cranks to a horizontal position until you hear a click, and the cranks no longer rotate.
- Fit the adapter handles by pressing the button on each adapter handle and sliding it onto the shaft of the upper extremity exerciser crank arm.
- Release the button and push the adapter handle onto the crank arm shaft until it clicks. The handle should now be locked in place.

The adapter handles are not designed to support the full weight of the body. They should not be used to move or carry the Omnicycle® Elite.

## Armrests

The armrests are a useful option to accommodate patients with symptoms of paralysis, hypertonia, muscle spasms or lack of hand/arm mobility to obtain a secure hold. Armrests can and should be individually adjusted. Combinations of armrests or the use of only one armrest is possible. Adjustment by a clinician is essential. Elastic Velcro® straps allow the forearms to be secured in the armrests. You can either place the arm in the armrest after the armrest has been attached to the upper extremity exerciser, or affix the armrest to the arm first and then slide the armrest onto the spindle on the crank.

## Adjusting the Position of the Control Pad

The position of the control pad on the Omnicycle® Elite upper extremity exerciser can be adjusted to suit the size and sitting position of the patient. Adjust the terminal by placing your hand on the top surface and either push or pull to position as needed.

For transportation, the control pad can be folded back/down completely.

## Changing the session time

When an exercising session is in progress, two buttons for changing the session time are shown at the bottom left and right of the screen. Pressing the + button increases the session time. To increase the session time in one second increments, press and release the button. Pressing and holding the + or – button increases/decreases the session time continuously up/down to the maximum/minimum.

## Start/Stop feature

When in “STAND-BY” mode, the Omnicycle® Elite is activated by pressing any button. The screen then lights up. Following a self-test lasting about 5 seconds the Omnicycle® Elite is ready for use. Pressing the “START” button then initiates the exercise session using the basic settings. The Omnicycle® Elite defaults to a set speed of 10 rpm. By actively turning the cranks at a speed greater than that of the motor, you can change over to active exercising at any time. You can “PAUSE” an exercise session in progress by pressing the “STOP” button once and resume it by pressing the “START” button. Pressing the “STOP” button twice during an ongoing exercise session ends the session. The display then shows the Exercise Summary data for that exercise session.

## Thermal Strip Printer

The Omnicycle® Elite has an external Bluetooth® controller for wireless communications with the thermal strip printer. From the display screen, the user has the option of sending the Exercise Summary Report to the printer to produce a hardcopy of the data for patient notes and/or documentation. The printer features one touch controls utilizing one button for power and paper feed. Press and hold the button to power down, or simply allow the printer to power off when idle.



## Cycle Set-Up for Operation

The following items should be checked prior to operation of the Omnicycle® Elite:

- The Omnicycle® Elite is intended for supervised use only
- When positioning the cycle, always place on a level/non-slip surface
- Route the power cord appropriately to prevent a trip hazard, entanglement with cranks, or damaged to other adjacent equipment
- Never use the cycle in wet, damp, or overly hot conditions
- Always use the Omnicycle® “anti-tip straps” when using the system with wheelchair bound patients to avoid the possibility of a tip-over or injury.
- Never attempt to adjust, grasp, or stop moving parts while the system is in operation (i.e.: cranks, crank length adjusters, footrest, calf length adjusters or armrests).

## Setting up the Exercise Program

Determine whether upper or lower extremity exercise is indicated:

Each has a separate motor.

- They cannot be used simultaneously.
- Operation is selected on the main operational screen of the system (the display shows a foot, a pedal, or a hand).
- The system defaults to the “NEURO” mode of operation unless “ORTHO” or “CARDIO” is selected from the available menu choices.
- For added stability, the stand on your Omnicycle® Elite should be extended. See extended stand in picture to the right.
- Your Omnicycle® Elite is equipped with the anti-tip restraint straps, ensure the hooks are correctly fixed to the wheelchair to help prevent it from tipping. See strap placement in picture to the right.



## Setting up the Exercise Program – Lower Extremity

Use the Assisted Entry feature if needed to help position the patient (press the foot icon on the display to rotate the pedals to load the patient)

- The Omnicycle® will automatically move each pedal into a position where it is easy to put the patient’s feet in place.
- Push the Assisted Entry button and wait until the footrest has rotated to its lowest position, then place the foot in position and apply Velcro® straps to fit
- Repeat for the other foot.
- Secure the calf support belts as needed when the foot is in the upper position.



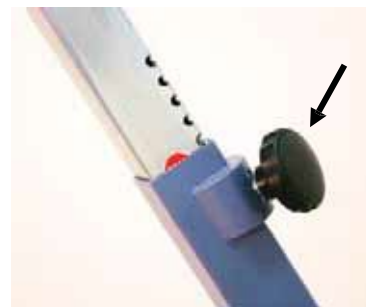
Next, position the patient and check peddle/arm crank clearances

- In cases of contracture or in order to limit joint movement, adjust the LE pedal length. This can be done for each side independently. First, turn the system “OFF” - Do not adjust when the motor is running. Remove the patient’s foot from the footrest and adjust length as needed. Make sure the pedal is tight using the locking screw.
- Rotate the footrests by hand (without the motor) through one full revolution with the patient’s feet in position and the legs strapped-in to ensure that the cranks can move freely, that the crank length is correctly set, and that leg movement is not restricted.



Next, adjust the handlebar, if needed

- Set the height of the handlebar/upper extremity exerciser so that the patient’s thighs cannot come in contact with the handlebars/arm cranks at any point during the LE pedal rotation.
- To adjust the height, undo locking screw knob on support tube by turning counterclockwise then pull to release the pin from the channel; adjust height, release knob and turn clockwise to re-tighten knob. Make sure it is fully tightened.
- The pedals and handlebars should not be used as a support for standing. The cycle could tip over.



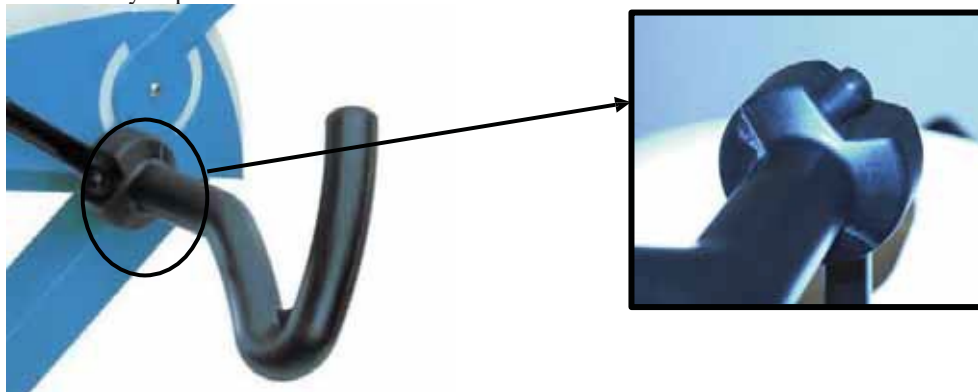
Ensure that patient can comfortably grip the handle. The straight handle should be used with the upper extremity locked when performing lower extremity exercise. Rotate the patients legs through one complete revolution to verify that there are no restrictions or pinch points before beginning the exercise program.

### Setting up the Exercise Program – Upper Extremity

Ensure that the patient can comfortably grip the handle. Make sure that the upper extremity handles are not locked. Use the assisted entry feature if needed to help position the patient (press the foot pedal button).



- To change the handles, depress the pin on the handle (pictured below). The armrest or handles can then be removed. On replacement, the new handles will automatically snap into place. Make sure the handles are securely in place before use.



- Use the armrest pictured below for patients with limited mobility. Make sure the patient's arms are comfortably secured with the Velcro® assisted straps.



**WARNING:** *Never select the start button until it has been verified that the upper extremity icon is selected. Serious injury to the user or patient could result when the lower extremity is selected if the patient's legs are in front of the pedals.*

**WARNING:** *Never operate the lower extremity exerciser with the pedals removed. Serious injury to the user or patient could result. The patient's feet should be strapped into the pedals or wheelchair footrests at all times. Make sure there is ample clearance between the handles and the patient's knees.*

**CAUTION:** *When using the molded armrest, make sure that the patient's thumb is strapped down so it does not come in contact with the display terminal while exercising in Upper extremity mode.*

Rotate the handles by hand (without the motor) through one full revolution with the patient's arms in position and the legs comfortably placed in the pedals (using the Velcro® assisted straps and calf support as needed) or wheelchair footrests. Ensure that the cranks can move freely, and that movement of the arms is not restricted before starting the exercise program.

## Assisted Entry

The assisted entry function is used to move each pedal's position to make it easier to properly secure the patient's feet in the footrests/calf support.

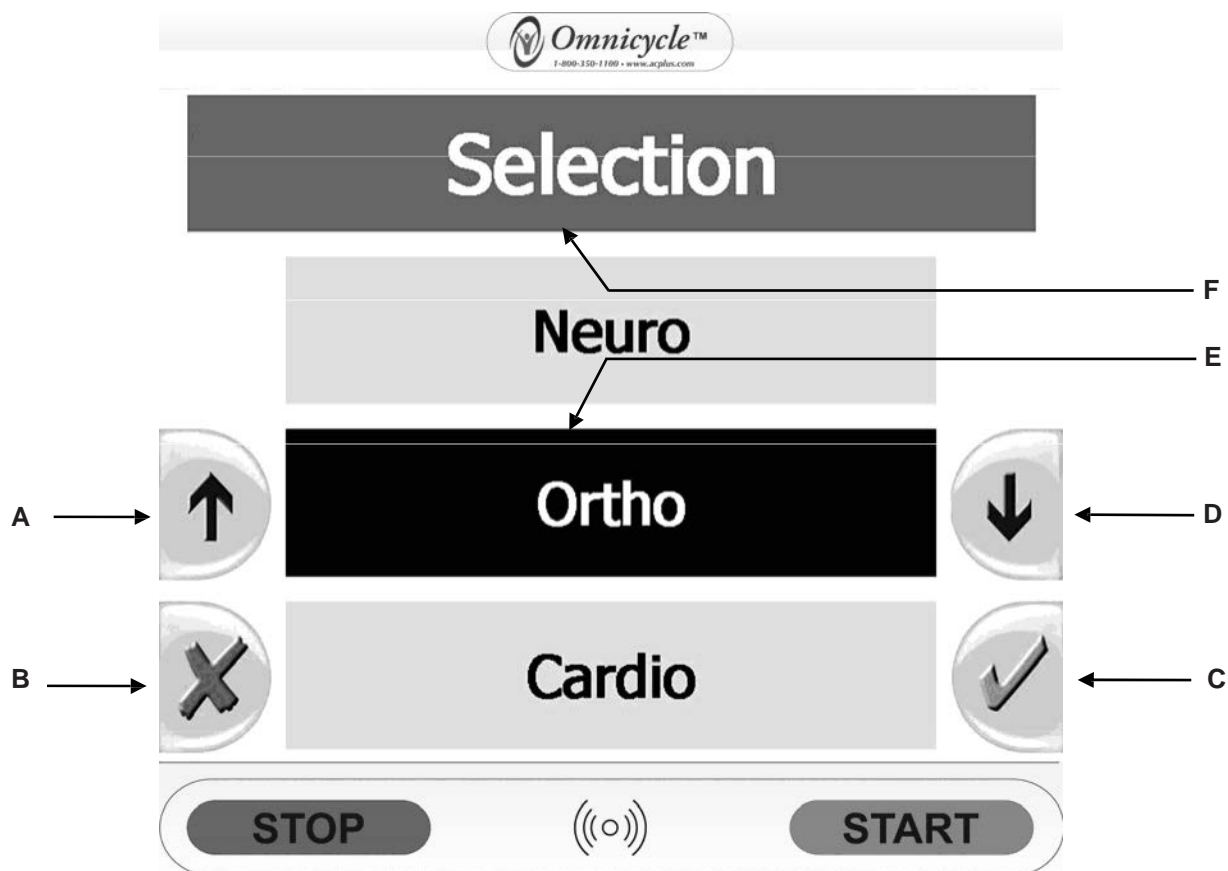
- Press the pedal icon once and wait until the footrest has stopped moving.
- Place the first foot in the footrest that is closest to the patient.
- Press the button again and wait for the other footrest to move to the position closest to the patient.
- Secure the first foot in the footrest at the top and then place the second foot closest to the patient.
- Press the button again and wait for the footrests to reach the first position again. Now secure the second foot.

## OMNICYCLE® ELITE PROGRAM MENU

The Omnicycle® Elite has a number of exercise programs that are based on the needs of typical patient groups. For each patient group, the exercising parameters can be set on a submenu.

The complete menu structure is shown below.

**Navigating the submenu** - To open the submenu; press the wrench icon on the main menu. The submenu items: Neuro, Ortho, Cardio, Soccer, Porcupine, Traffic, and System (Configuration) are displayed.



- A. Up/More** - This button scrolls the display up. In the case of menu items which require entry of an amount (e.g. motor power), this button increases the setting.
- B. X Cancel/Discard changes** - This button takes you back up to the next higher menu level. Any changes previously saved by pressing **Save Changes** button are retained; those not saved by pressing **Save Changes** are lost.
- C. '1 Save Changes/Continue** - This button saves your settings. If the menu item selected has further options, this button takes you to the next menu option.
- D. Down/Less** - This button scrolls the display down. The menu item selected is highlighted by inverted colors. In the case of menu items which require entry of an amount (e.g. motor power), this button decreases the amount.
- E. Current selection** – is identified by the reversed color relative to other selections.
- F. Current submenu item** – is displayed on top.



## Full Program Menu

The parameters of the exercising programs and systems settings are set out within the following menu structure:

1 <sup>st</sup> Level	2 <sup>nd</sup> Level	Adjustable Settings/Functions	Factory Default Settings
<b>NEURO</b>			
	Duration	1 to 60 minutes	15 minutes
	Forward/Backward auto	On/Off	Off
	Biofeedback	Symmetry bar/road, Active Assist, Off	Symmetry bar
	Motor power	2 to 22 Nm	15 Nm
	Spastic detector	Fine / Medium / Rough	Rough
	Spastic autom.	Forward/Backward/Change/Follow	Follow
	Speed adaption	On/Off	Off
	Heart rate limit	60 to 160 bpm	100 bpm
<b>ORTHO</b>			
	Duration	1 to 60 minutes	15 minutes
	Biofeedback	Symmetry bar/road, Active Assist, Off	Symmetry bar
	Motor power	2 to 22 Nm	15 Nm
	Muscle support	Off/On	On
	Heart rate limit	60 to 160 bpm	100 bpm
<b>CARDIO</b>			
	Duration	1 to 60 minutes	15 minutes
	Biofeedback	Symmetry bar/road, Active Assist, Off	Symmetry bar
	Motor power	2 to 22 Nm	15 Nm
	Heart rate limit	60 to 160 bpm	100 bpm
<b>SOCCER</b>			
	Duration	1 to 60 minutes	15 minutes
	Level	Minimal , Moderate, Maximum	Minimal
	Motor power	2 to 22 Nm	15 Nm
	Spastic detector	Fine / Medium / Rough	Rough
	Heart rate limit	60 to 160 bpm	100 bpm
<b>PORCUPINE</b>			
	Duration	1 to 60 minutes	15 minutes
	Level	Minimal , Moderate, Maximum	Minimal
	Motor power	2 to 22 Nm	15 Nm
	Spastic detector	Fine / Medium / Rough	Rough
	Maximum symmetry	70%,80%,90%,100%	80%
	Heart rate limit	60 to 160 bpm	100 bpm
<b>TRAFFIC JAM</b>			
	Duration	1 to 60 minutes	15 minutes
	Level	Minimal , Moderate, Maximum	Minimal
	Motor power	2 to 22 Nm	15 Nm
	Spastic detector	Fine / Medium / Rough	Rough
	Lane preselection	Right / Left / Random	Random
	Heart rate limit	60 to 160 bpm	100 bpm
<b>SYSTEM</b>			
	Sensitivity mike	0 to 10	2
	Language	Multiple Languages	English (US)
	Contrast	1 to 40	15
	Configuration	Control Panel with Program Counters	Default
	Set parameters as default		

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## Description of Omnicycle® Elite Functions

This Sub Menu level allows the user to select from the following exercise modes:

- Neuro
- Soccer
- System (Configuration)
- Ortho
- Porcupine
- Cardio
- Traffic Jam

**Neuro:** (basic setting): Exercise programs for patients with neurological conditions, e.g. hemiplegia, paraplegia, MS, and Parkinson's disease. This exercise mode includes a pre-set resistance level that remains constant regardless of the patient's pedaling speed. Higher pedaling speeds mean greater power output.

**Ortho:** Exercise programs for orthopedic patients, e.g. following a knee or hip injury or surgery. This exercise mode includes a constant power level. When the patient is given a set power level at which to exercise, the Omnicycle® Elite automatically modulates the resistance according to the pedaling speed so that the amount of power required is always the same.

**Cardio:** Exercising programs for cardio-vascular patients whose heart rate must be kept below a certain limit. In Cardio exercising mode, a heart rate limit is set and the system operates in a constant power mode. The Omnicycle® Elite reduces the resistance as soon as the patient's heart rate reaches that limit.

**Soccer:** Biofeedback is used to create an interactive exercise experience that encourages greater patient motivation, exercise effort, duration, and performance by increasing or decreasing pedal RPM to position the goalie and prevent the ball from entering into the net. The program requires the patient to maintain the goalie's position within the area of the net by maintaining a pre-set RPM range (minimum, moderate and maximum). When the patient's work RPMs fall below the set parameter range, the goalie falls below the net. The movement of the goalie responds only with "active" exercise by the patient. In the "assisted" exercise mode, the pedal RPMs are limited to 1-15 in minimum, 1-25 in moderate, and 1-35 in maximum. The set resistance level remains constant regardless of the pedaling speed.

**Porcupine:** Biofeedback is used to create an interactive exercise experience that encourages greater patient motivation, exercise effort, duration, and performance by varying right/left pedal force output. This exercise activity requires the patient to control the position of the Porcupine (left, right, center etc.) by peddling with more force on the side (left or right) required to position the Porcupine beneath or next to the falling target (balloon, paper airplane etc.) Peddling symmetrically will hold the position of the Porcupine. The set resistance level remains constant regardless of the patient's pedaling speed.

**Traffic Jam:** Biofeedback is used to create an interactive exercise experience that encourages greater patient motivation, exercise effort, duration, and performance by varying pedal right/left pedal force output. This exercise requires the patient to peddle left, right or symmetrically to avoid vehicles on the screen. The patient "steers" their vehicle (car) left or right by peddling with more force on the side required to position the Car to avoid crashing the vehicle in front or to the side of him. Overtaking or passing vehicles requires symmetrical peddling. An adjustable parameter called "Lane preselection" enables the operator to select whether the vehicles to be avoided will appear on the right, left or randomly. Using the minimum level of difficulty, no other cars appear in adjacent lanes and the patient is simply required to keep their car positioned in the center lane. The set resistance level remains constant regardless of the pedaling speed.

**Virtual Cycling:** This is a Bluetooth® connected exercise for future development where users are able to connect to the OmniVR® Virtual Rehabilitation system to compete in interactive exercises. Biofeedback is used to create this interactive exercise experience that encourages greater patient motivation; exercise effort, duration, and performance by increasing or decreasing pedal RPM to control characters on the screen. Refer to the OmniVR® User Manual or contact ACP Customer Support for additional information.

**System Controls:** This Sub Menu option also allows the operator to adjust settings for microphone sensitivity, language, and contrast. The configuration option allows viewing of the motor, protocol timers, and establishing default settings.



PROGRAM	INDICATIONS	DESCRIPTION
<b>Neuro</b>	Exercise for patients with neurological conditions (e.g. post-stroke, MS, and Parkinson's Disease)	With this mode of exercise the therapist sets a resistance level. The resistance level remains constant regardless of pedaling speed. Higher pedaling speeds mean greater power output.
<b>Ortho</b>	Exercise for orthopedic patients (e.g. status post total knee, total shoulder, hip fracture)	With this mode of exercise the therapist sets a power level. The <i>Omnicycle®</i> varies the resistance automatically according to the pedaling speed so the set power output remains the same. Therefore, the resistance decreases when the patient pedals faster and the resistance increases when the patient pedals slower.
<b>Cardio</b>	Exercise for patients with cardiac issues (e.g. status post MI, CAD, hypertension)	With this mode of exercise the therapist sets a target heart rate. The patient wears a cardiac monitor. The cycle resistance automatically decreases if the target heart rate is exceeded.
<b>Soccer</b>	Interactive Biofeedback activity encourages greater patient motivation, participation, and performance by varying pedal RPM. May facilitate cardiovascular, muscle, ROM, and/or cognitive exercise-related goals	By pedaling faster or slower (RPMs) the patient controls the position of a goalie to prevent a soccer ball from going into the goal net. The RPMs required to position the goalie are pre-set at minimum, moderate, or maximum levels of difficulty. When the RPMs (patient effort) fall below the set parameter range, the goalie drops below the goal area. When the RPMs exceed the set upper parameter range, the goalie moves above the goal area. In the "assisted" exercise mode, the pedal RPMs are limited to 1-15 in minimum, 1-25 in moderate, and 1-35 in maximum. The set resistance level remains constant regardless of the pedaling speed.
<b>Porcupine</b>	Interactive Biofeedback activity encourages greater patient motivation, participation, and performance by varying pedal right/left pedal force output. May facilitate cardiovascular, muscle, ROM, and/or cognitive exercise-related goals	By varying the amount of force applied to the right and left pedals, the patient controls the position of a porcupine (right and left). The goal of the exercise is to position the porcupine under as many falling objects as possible (balloon, paper airplane, etc.). Equal force on the right/left pedals holds the porcupine in the position necessary to intercept the falling objects. The set resistance level remains constant regardless of the patient's pedaling speed.
<b>Traffic Jam</b>	Interactive Biofeedback activity encourages greater patient motivation, participation, and performance by varying pedal right/left pedal force output. May facilitate cardiovascular, muscle, ROM, and/or cognitive exercise-related goals	By varying the amount of force applied to the right and left pedals, the patient moves ("steers") a car through traffic. The goal of the exercise is to drive the car without hitting any vehicles that appear along the way. Overtaking or passing vehicles requires even distribution of forces applied to the right and left pedals. An adjustable parameter called "Lane Preselection" enables the operator to select whether the vehicles to be avoided will appear on the right, left, the center lane, or randomly. By selecting the minimum level of difficulty, no other cars appear in adjacent lanes and the patient is simply required to keep the car positioned in the center lane. The set resistance level remains constant regardless of the pedaling speed.

## Menu Features

**Duration:** (Exercise time) the length of the exercise session can be set to between 1 and 60 minutes in all exercise modes. The default setting for each mode is 15 minutes.

**Forward/Backward/Auto:** (Automatic direction reversal) A “Neuro” function. When this function is active, the system automatically changes the direction of rotation every four minutes **when the patient is exercising in “assisted” mode**. When the patient is exercising in “active” mode, the direction of rotation is not reversed.

**Biofeedback:** The purpose of the Biofeedback function is to provide the patient with feedback about the progress of the session or the interactive exercise activity they are participating in. The system has biofeedback settings in Neuro, Ortho, Cardio, Soccer, Porcupine, and Traffic Jam exercise activities. All biofeedback options have the following features:

- Current resistance/RPM setting
- If a heart rate sensor is connected, the current heart rate is displayed
- The patient’s current RPM output
- The distance completed
- The remaining exercise time

**Biofeedback Settings:** These settings are available under the Neuro, Ortho, and Cardio programs.

**Symmetry Bar/Road:** These two biofeedback diagrams show how symmetrically “active” exercising is being performed, which allows the patient/operator to detect the power difference between the right and left legs for each pedal rotation. The bar diagram shows the distribution of power output between the two sides. The total of the two bars always adds up to 100%. These modes are used to retrain Right-Left function, motor control and symmetry.

Using the “Road” function, a bicycle moves to the left or right of the road based on the patient’s power output between the left and right sides. In addition, the pedaling speed is indicated by the speed at which the dotted line down the middle of the road moves. At irregular intervals, obstacles appear on the road that the patient must avoid by applying more power to one leg or the other. If an obstacle is “avoided” by appropriate “one-sided” exercising (obstacle on the left --- more activity on the right) the obstacle changes to green.

**Biofeedback Programs:** These programs are available on the main screen on the program selection bar.

**Soccer, Porcupine, and Traffic Jam:** These biofeedback-based interactive exercise programs are selectable from the Main Menu Program Selection Bar at the top of the display screen. These programs operate separate of the Neuro, Ortho, and Cardio programs. Settings are all adjusted under the wrench icon from the main menu.

The biofeedback results can be affected if:

- The cranks are not adjusted to the same length on both side
- The patient’s seat is not centrally positioned relative to the Omnicycle® Elite
- A leg is “pulling” as well as “pushing”

Only select biofeedback programs are not available for the upper extremity exercise programs. This is because the upper extremity exerciser is normally a push/pull exerciser. It will not display the left/right side weaknesses.

**Active Mode Display:** When the patient is exercising in “active” mode, the color display screen shows a bar illustrating the amount of motor power that is being used to move the patient’s legs. After a minute of warm-up, the patient should be encouraged to begin exercising on their own. A line will appear on the screen and a percentage of exercise. The “START” button shows the starting level during the first minute of exercising. The filled section of the bar and the percentage figure at the bottom show what percentage of the set motor power is currently being used to move the legs. This mode is used to promote relaxation of the muscle tone in the lower extremities.

Changing the crank length has a substantial effect on the Biofeedback function and the data it displays. The percent of max motor-assist figures captured from two different exercising sessions are only comparable if the crank length and the maximum motor power (Sub Menu) settings are the same for both sessions.

**NOTE:** The data is used to show the patient how tight or loose patient limbs are or if muscle hypertonia has been reduced.

**Motor power:** The set motor power (torque) has a greater effect on the patient's legs with a smaller crank length than with a longer crank length. The motor power setting limits the motor's maximum torque output. It can be set to between 2 and 22 Nm. Set the motor power as follows:

① To ⑥ = Adjustable crank length settings

①

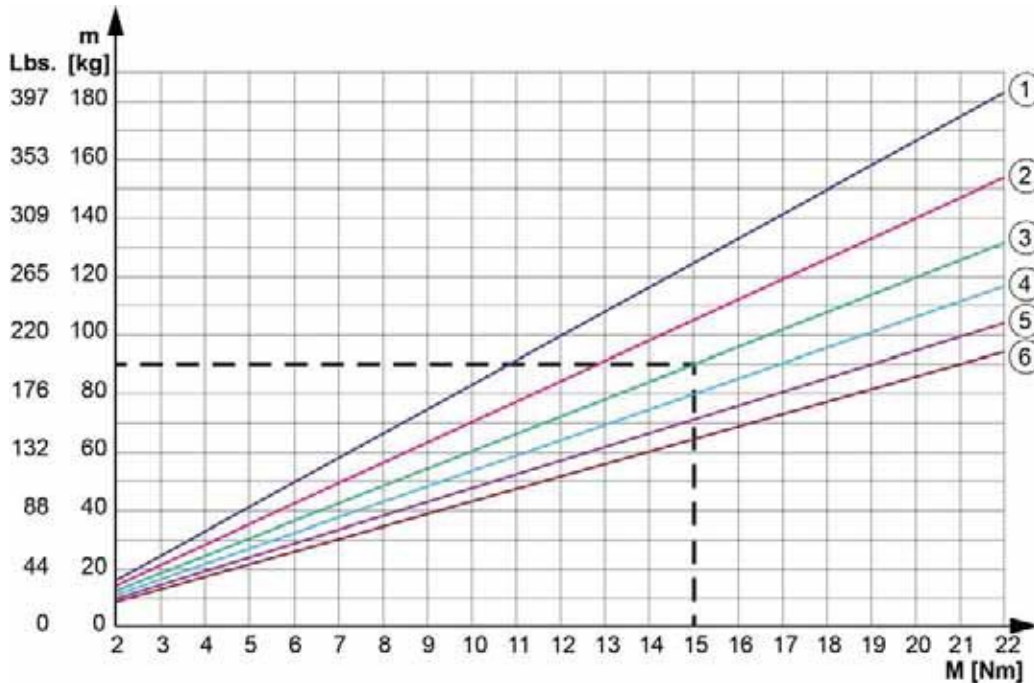
① = Very short crank length

⑥ = Very long crank length

Lbs. = Mass (weight) of patient

M = Motor torque (power setting)

**NOTE:** With a short crank length and a high motor power setting, the patient can be subjected to very strong forces. The motor power for the upper extremity exerciser is approx. 30% of the power of the lower extremity exerciser.



**Spastic detector:** A “Neuro” function. This setting is used to specify the threshold at which the Omnicycle® Elite sensors detect a spastic reaction on the part of the patient and stops the motor to minimize the risk of overstressing the patient. For patients who may be subject to spasms, there are three different settings that may be used based on specific symptoms or physical limitations:

- **Fine** for patients with very sensitive joints and tendons. At this setting even very slight resistance is enough to stop the motor.
- **Medium** for patients with less sensitive responses.
- **Rough** for patients with pronounced spasticity. The exerciser does not stop until there is a large amount of resistance.

**NOTE:** The longer the crank length or the lower the motor power, the more sensitively the spasticity detection responds. The shorter the crank length/the greater the motor power, the less sensitively the spasticity detection responds.

**Spastic Automation:** A “Neuro” function. The Spastic Automation function is used to set the direction of rotation following detection of a spasm. Select from the following options:

- **Forward** if the patient tends to suffer extension spasms
- **Backward** if the patient tends to suffer flexion spasms
- **Change** to have the exerciser rotate in the opposite direction to the direction it was rotating when the spasm was detected
- **Follow** to have the exerciser rotate in the same direction it was rotating when the spasm was detected

**Speed Adaptation:** A “Neuro” function. If Automatic Speed Adaption is set to “ON” the “assisted” exercising (motor) speed automatically adjusts to greater effort by the patient when exercising “actively.”

**Example:** If a patient is exercising in “active” mode” at 50 rpm when the motor speed (“assisted” exercising speed) is set to 20 rpm, after every 10 seconds, the Omnicycle® Elite adjusts the “assisted” exercising speed upward by 1 rpm to a maximum of 35 rpm. If the patient subsequently changes back to “assisted” exercising, the Omnicycle® Elite drops the speed to 5 rpm lower than the active speed, or 30 rpm, whichever is lower. Thus the patient individually controls the speed and obtains an “assisted” exercising speed at which he/she is comfortable.

**Heart rate limit:** The Omnicycle® Elite reduces the resistance level as soon as the pre-set heart rate limit is reached. This is to ensure that the patient always exercises at a heart rate below the pre-set limit.

**NOTE:** *Because a high level of effort is required for all Ortho and Cardio exercising programs, using a long crank length is advisable.*

**Level:** This function applies to the biofeedback-based exercise programs Soccer, Porcupine and Traffic Jam. This function allows the operator to choose a difficulty setting of minimal, moderate or maximum.

**Maximum Symmetry:** Available for lower extremity Porcupine program. Allows the operator to adjust how close the Porcupine will be positioned from the edge of the border by percentage (70% 80% 90% 100%). At 100% the Porcupine will be at edge position of the border.

**Muscle Support:** An “Ortho” function. This function assists patients with only minimal residual strength or minimal strength on one side. The residual strength is supplemented by this function so that an even pedaling action is always obtained. The function operates according to the principle of “as much assistance as necessary but as little assistance as possible.” The objective of this function is to optimize the patient’s exercise effort at all times and to achieve greater symmetry.

**NOTE:** *In the case of leg-amputee patients, the Muscle Assistance function performs the work of the inactive side. In such cases, the Muscle Assistance function operates like an “electronic flywheel”.*

**Sens. Mic:** (Microphone sensitivity) A System function. The Omnicycle® Elite can be stopped by a long, loud shout (safety voice deactivation). This function is particularly useful for patients who use the upper extremity exerciser with their arms strapped to the armrests and cannot, therefore, use the control pad. The safety voice deactivation function is always active. The menu option Technical/Microphone sensitivity allows you to set the sensitivity of the integrated microphone in the control pad. Set the sensitivity as follows:

- 1 to 3 if the ambient noise is very loud
- 4 to 6 if the ambient noise is of a normal level
- 7 to 10 if the ambient noise is very quiet
- OFF if the therapist wishes to deactivate the microphone

**NOTE:** *Check that the setting is correct by carrying out a practical test. Afterwards press the “START” button to continue the exercising session.*

**Contrast:** The contrast of the color screen is set at the factory. If necessary, it can be adjusted by selecting the menu option “Technical/Contrast.”

**Analysis of Session Data:** At the end of an exercising session, an analysis of the session data is displayed (Exercise Summary). The data is only calculated if the session has lasted for at least one minute and was started by pressing the START button. The following data is displayed:

- **Duration:** total length of exercising session (in minutes) excluding “PAUSE”
- **Active proportion** (patient’s efforts): proportion of the total time (in %) during which the patient was exercising by his/her own efforts.
- **Activity, left:** proportion of activity for the left leg (in %).
- **Activity, right:** proportion of activity for the right leg (in %).
- **Distance:** total distance completed (in km).
- **Number of spasms:** number of spasms detected during the exercising session.
- **Calories:** number of calories consumed (in kcal).
- **Starting motor power:** assistance (muscle hypertonia) at the start of the exercising session (during the first 60 seconds)
- **Finishing motor power:** assistance (muscle hypertonia) at the end of the exercising session

Pressing the “STOP” button takes you back to the basic display.

**Resetting the Basic Exercise Settings/Defaults:** The Omnicycle® Elite is delivered with default settings. The cycle also has the ability for the user to set predetermined default settings using the “Set Params” setting in the Selection Menu.

If any settings are changed on the Selection Menu, without setting them to default, those changes are retained until the power is switched off, power has been disconnected, or the settings are changed manually. This means that the same settings can be used for the next exercise session until changed or power has been interrupted.

If you wish to reset the Omnicycle® Elite to the user predetermined setting, proceed as follows:

- Press the “Reset to Default” button to reset the Omnicycle® to restore user default settings.
- The Omnicycle® Elite will revert to the user predetermined default settings, and the display will read “Reset to Default”.

If you wish to reset the Omnicycle® Elite to the factory settings, proceed as follows:

- Press and hold the “STOP” button, while pressing the “Reset to Default” button to reset the Omnicycle® to restore default settings.
- The Omnicycle® Elite will revert to the factory default settings, and the display will read “Settings Restored”.

#### Biofeedback Program Levels:

SOCCER EXERCISE LEVEL	MINIMAL	MODERATE	MAXIMUM
Ball size	Big	Medium	Small
Ball speed	Slow	Faster	Fastest
Active RPM Range required to position the goalie in the net	20-35	30-45	40-70
Assisted RPM Range placing the goalie below the new	1 -15	1-25	1-35

TRAFFIC JAM EXERCISE LEVEL	MINIMAL	MODERATE	MAXIMUM
Number of vehicles	0	1	2

PORCUPINE EXERCISE LEVEL	MINIMAL	MODERATE	MAXIMUM
Rate of descent falling target	Slow	Faster	Fastest



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## INFECTION CONTROL EQUIPMENT AND PRINCIPLES OF USE

### Definitions

- **Barrier Film** – One-time use, disposable plastic film for use over touch/operator surfaces of equipment to reduce risks of cross-contamination and need for high level disinfection of equipment between patients.
- **Germicidal Disposable Wipe** – Low level and/or intermediate level disposable germicidal disinfectant wipe for use on electrotherapeutic devices and accessories.

### Universal Precautions – Body Substance Isolation

Universal Precautions (UP) must be implemented in the care of all patients to protect employees from occupational exposure to blood borne pathogens. Personal protective equipment (gloves, masks, gowns) should be available and worn by staff when occupational exposure to blood, body fluids containing blood, semen and vaginal secretions is likely to occur. Health care workers with exudating lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment until the condition resolves. Equipment must be cleaned/disinfected and protective barriers used when appropriate.

### Cleaning/Disinfecting of the Omnicycle® Elite

Therapy equipment shall be cleaned / disinfected per facility infection control policy. ACP recommends the following guidelines:

#### Cleaning and 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 and urine.

- Clean equipment daily with ACP germicidal wipes. At the end of the day, wipe common contact surfaces, such as control panel, with germicidal disposable wipe 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.

#### Intermediate Level Disinfection and Barriers

These methods are recommended to keep the equipment clean and free of contaminants when used between patients for treatment of non-intact skin or incontinence management, where there is an increased risk of patient cross-contamination. The following are the recommended practices.

- After each use, clean common contact surfaces, such as the display screen, with ACP germicidal wipes.
- With a second ACP germicidal cloth, wipe again leaving surfaces wet for at least 5 minutes. Allow the surface to air dry before patient use.
- Barriers should also be used on the equipment for treatment of patients with non-intact skin or urinary incontinence. This technique will inactivate *M. tuberculosis* as well as most bacteria and viruses.

**NOTE:** *Always make sure the Omnicycle® Elite is unplugged from the power outlet before cleaning.*

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## Use of Barriers – Intermediate Level Disinfection

The use of an all-purpose barrier film provides surface protection from cross-contamination resulting from a variety of applications. This precaution should be used whenever dealing with non-intact skin or the chance of coming in contact with bodily fluids. Barrier film is designed to cover any surface that may be touched during patient therapy, in order to help prevent cross-contamination. Barrier film is for single-use only. The film is discarded after each patient therapy. The procedure for use is as follows:

1. Wash hands.
2. Apply Intermediate Level Disinfection prior to barrier application.
3. Select, tear or cut with clean scissors a length of barrier film to fit over the operator surfaces of the Omnicycle® Elite unit.
4. Prepare any items which may become in contact with the therapist during treatment, such as ultrasound gel, pens, assessment tools, cart handles, etc.
5. Set up the patient per guidelines for the therapy.
6. Provide therapy as appropriate.
7. Discard all disposables.
8. With clean gloves, remove the plastic film from the unit and discard.
9. Intermediate disinfect the Omnicycle® Elite unit prior to the next therapy application.

## TROUBLESHOOTING

The following table lists machine problem symptoms and possible areas to check for the problem causes. If these suggested measures do not correct the machine malfunction, call your ACP Customer Support at 800-350-1100.

PROBLEM	REMEDY
Omnicycle® Elite has too little power	<ul style="list-style-type: none"> <li>• Shorten crank length</li> <li>• Increase motor power one increment</li> </ul> <i>(Note: Be certain not to overstress joints and tendons)</i>
The spasticity detection responds too frequently	<ul style="list-style-type: none"> <li>• Reduce the sensitivity of spasticity detection</li> <li>• Shorten crank length</li> <li>• Increase motor power one increment</li> <li>• Optimize sitting position and distance from the unit</li> </ul> <i>(Note: Be certain to consult with your therapist to make sure your joints and tendons are not being overstressed)</i>
The resistance is too high for active exercising	<ul style="list-style-type: none"> <li>• In Neuro exercise mode, reduce the resistance</li> <li>• In Ortho or Cardio exercise mode, reduce the power setting</li> <li>• Increase the crank length</li> </ul>
The heart rate sensor does not work	<ul style="list-style-type: none"> <li>• Make sure that the heart rate sensor is properly connected</li> <li>• Make sure the heart rate sensor is properly positioned and/or moisten the heart rate sensor. Reposition the heart rate sensor.</li> </ul>
The Omnicycle® Elite runs unevenly	<ul style="list-style-type: none"> <li>• Switch ON muscle power assistance</li> <li>• Set equal crank length on both sides</li> <li>• Check that sitting position is central (relative to spindle)</li> </ul>
The Omnicycle® Elite does not start	<ul style="list-style-type: none"> <li>• Have you pressed “START” (twice if Omnicycle® Elite is in stand-by mode)? Screen may reset if in standby mode.</li> <li>• Check power cord. Unplug the power cord then reconnect.</li> <li>• Check power supply fuse</li> <li>• Select the correct exerciser (upper or lower body)</li> <li>• Unlock the upper extremity exerciser</li> </ul>
Exercise session analysis is not displayed	<ul style="list-style-type: none"> <li>• Exercise for at least one (1) minute</li> </ul>
Safety voice deactivation does not respond	<ul style="list-style-type: none"> <li>• Increase the microphone sensitivity</li> </ul>
Exercise settings have changed	<ul style="list-style-type: none"> <li>• Set new basic settings and save</li> <li>• Reset basic settings to factory settings</li> </ul>
LE / UE exerciser button has no effect	<ul style="list-style-type: none"> <li>• Check connection of upper extremity exerciser</li> </ul>
Symmetry bars / road diagram in Bio-feedback display shows obviously incorrect data	<ul style="list-style-type: none"> <li>• Set equal crank length on both sides</li> <li>• Check sitting position is central relative to spindle</li> <li>• Are you “pulling” instead of “pushing” with one foot?</li> <li>• The Omnicycle® Elite needs to be recalibrated</li> </ul>
Crank does not stop when using assisted entry function	<ul style="list-style-type: none"> <li>• Press STOP button to stop accidentally started exercising session, then press and hold START button at least 3 seconds</li> <li>• If problem persists, contact the Service Center</li> </ul>

### Replacing a fuse

1. Unplug the power cord from the machine
2. Using a small screwdriver, remove the power supply fuse cover.
3. Use the screwdriver to remove both fuse holders.
4. Remove blown fuses.
5. Insert fuses of the correct rating as per the rating plate in the fuse holders.
6. Replace fuse holder and fuses.
7. Replace power supply fuse cover.



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## Certificate of Conformance Inspection

Certificate of Conformance Inspection, consisting of an electrical safety check, is recommended to be performed at least biennially (every two years).

## Good Operating Practices

Users should follow and complete the following recommendations on an ongoing basis:

- Routinely check for power cord fraying or any other damage to the power cord.
- Check to ensure that the cycle ergometer is operating smoothly. Any change in the ergometer operation should be reported to the Service Center.
- Always check that the power cord, cardiac pickup and display control cables are properly routed and are not in danger of being snagged/pulled by the lower or upper cycle operation.
- Always keep the system clean and keep any debris, such as paper, string, cloth, or clothing away from the cycle moving parts.

## Servicing Your Omnicycle® Elite

For repair or service of ACP Products and accessories, please call (800) 350-1100 and follow the prompts. Normal hours of operation are 6:00am to 5:00pm Pacific Standard Time. After hours, please leave a message and a technician will return your call during the next scheduled workday.

## Proper Disposal

Proper disposal procedures shall be observed as required by specific state and/or local regulations. It is the responsibility of the owner of the device to follow applicable laws and regulation on disposal guidelines.

## TECHNICAL SPECIFICATIONS

GENERAL:		
Basic Omnicycle® Elite with upper extremity Exerciser	Length: Width: Height: Weight:	29 - 35 inches 18 inches 45.5 – 50 inches 90.4 pounds
Crank Length	Fixed: Variable:	3.0 inches / 4.3 inches 2.5 – 4.5 inches
Maximum Patient Weight Limit		265 lbs.
Patient Height Requirements		3' 11" to 6' 6"
Power Input	VAC	90 - 130
Power Supply Frequency	Hz	50 - 60
Speed Range	RPM	0 – 75
Speed Range Active Exercise	RPM	0 – 90
Torque Range	Nm	2 – 22
Fuse		2 X 1.6 AH 250V, slow
Noise Emission	dB	Lpa :S 70
Medical Device Class	FDA	Class I Exempt
Protection Class		I
Degree of Protection		Type B
Protection Category		IP2X
Ambient conditions for operation	°C % Rh hPa	5 to 40 15 to 90 700 to 1060
Ambient conditions for storage or transportation	°C % Rh hPa	-25 to 70 15 to 93 700 to 1060

*ACP reserves the right to change technical specifications and product availability without notice.*

## Electromagnetic Compatibility

The Omnicycle® Elite is delivered with a cardio pulse set manufactured by Polar®. This is the only pulse sensor that is authorized for use with the Omnicycle® Elite.

The Omnicycle® Elite meets the requirements of IEC 60601, IEC 61000, and CISPR11

The Omnicycle® Elite is not compliant to EN 60601-1-11 for Home Care purposes.

For best operation, the user should maintain a safe distance between the Omnicycle® Elite and other devices that transmit high frequency (i.e cellphones and wireless internet devices). A distance of thirty feet is recommended to reduce the likelihood of interference.




For a more comprehensive understanding of the Omnicycle® Elite with respect to EMC testing results. Please contact ACP Customer Support at (800) 350-1100. Ask for Document EMC-0100.

## OMNICYCLE® ELITE STANDARD AND OPTIONAL ACCESSORIES

ITEM	ITEM NO.	DESCRIPTION
	<b>A000-533</b>	<p><b>OMNICYCLE® ELITE MOTORIZED THERAPEUTIC REHABILITATION SYSTEM</b></p> <p>Offers lower extremity and upper extremity rehabilitation and exercise options, Biofeedback training, and Spasticity detection with color display screen.</p> <p><b>Shipping Weight: 100 lbs. (45 kg)</b></p>
ACCESSORY	ITEM NO.	DESCRIPTION
	<b>* 51123</b>	Glove-attachment
	<b>39222</b>	Cardio-Pulse Set with transmitter, receiver, coiled cord and straps (T34)
	<b>* 60239</b>	Molded arm rest attachment - Left
	<b>* 54565</b>	Molded arm rest attachment - Right
	<b>* AP1300-BT</b>	Thermal Printer, Bluetooth®
	<b>65168</b>	Omnicycle® Elite User Manual

*\* This item is an optional accessory and may not be included with the unit.*

## Infection Control Supplies

ITEM	ITEM NO.	DESCRIPTION
	52479	Barrier Film for Surfaces, Infection Control, 4" x 6" perforated sheets – 1200 sheets/roll
	66431	Barrier Film for Surfaces, Infection Control, 6" x 9" perforated Sheets – 1200 sheets/roll
	50593	Barrier Film - for Surfaces, Infection Control, 12" x 14" perforated Sheets – 800 sheets/roll
	63574	Barrier Film, 3" Tubing, 1200'/roll
	55536	Super Sani-Cloth®, Single Use Packets (50 pk/bx)
	44425	Super Sani-Cloth®, Tub (160/Tub)
	96849	Sani-Cloth® w/ Bleach, Tub (75 wipes/tub)

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## 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 Buyer 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 one (1) year 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 six (6) months 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 Support 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.

### 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 Support 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. PLEASE CALL CUSTOMER SERVICE AT (800)-350-1100 FOR AUTHORIZATION. EQUIPMENT SENT IN WITHOUT AUTHORIZATION FROM ACP CUSTOMER SUPPORT WILL NOT BE ACCEPTED.**

**Returned Materials Shipping Address:**

Accelerated Care Plus  
Attn: ACP Service Center  
4999 Aircenter Circle, Suite 103  
Reno, NV 89502

## APPENDIX I - ILLUSTRATED OPERATIONAL SEQUENCE

### Procedure for Quick Start-Up

The following procedure can be used when the programs are going to be used as pre-set in the Omnicycle® Elite, and when there is no need to modify the parameters.

When the cycle is in STAND-BY mode or is not turned on, the Omnicycle® Elite can be activated by pressing any button on the control panel. The screen will light up. During a self test, which lasts about five (5) seconds, the welcome screen is displayed, followed by the system version screen. After the self test, the unit will display the following start screen:

The Omnicycle® Elite is now ready for use. Pressing the START button at this point will start the exercise session with the basic default settings, with the pedals going at 10 rpm in assisted exercise mode. By actively turning the pedals at speeds greater than this, the cycle will change to active exercise mode at any time.

By pressing the STOP button once during the exercise session, the Omnicycle® Elite will pause. It will resume the same session when the START button is pressed.

When the START button is pressed, and the cycle has started the exercise session, the following screen will be displayed:

The DURATION will display the time remaining in the started exercise session, and will count down to zero, at which time the cycle will sound an audible tone and stop. The exercise session activity report screen will be displayed.



## Submenu Operation

Follow this procedure for detailed instructions on adjusting parameters for selected programs.

### SELECTING PROGRAM:

The Omnicycle® Elite has a number of exercising programs that are based on the needs of a typical patient group. For each patient group, the exercising parameters can be selected and set on the submenu.

To enter the submenu, from the main start up screen, press the wrench icon.



The following screen will be displayed:

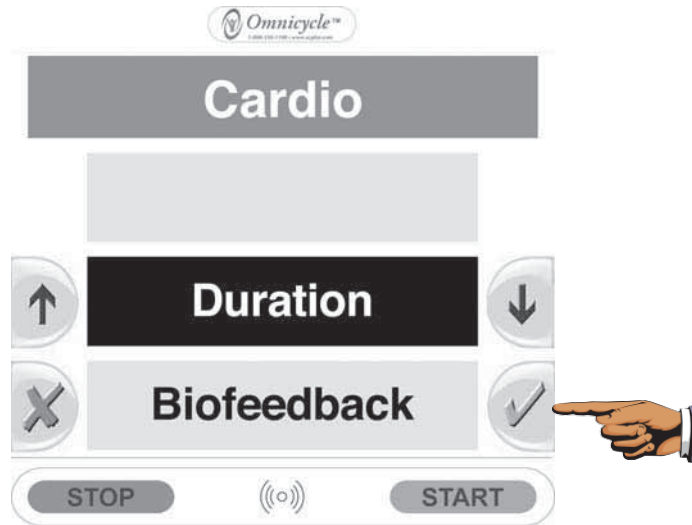


Pressing the UP or DOWN arrows will scroll the screen thru the available main programs: Neuro, Ortho, Cardio Soccer, Porcupine, Traffic Jam, and System. To select the desired program, press the CHECK MARK ('1') button when that program appears in the screen center, and is identified by the black color of the program name box.

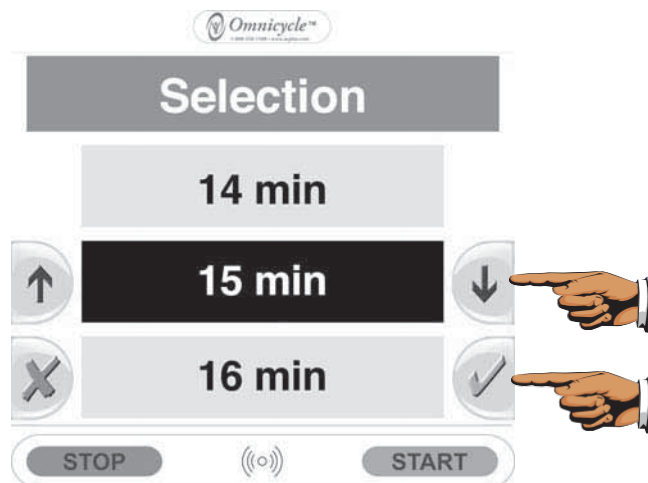


## Adjusting parameters for a selected program:

In the example below, the Cardio program was selected. The following screen will be displayed:



The following choices are then available for the Cardio program: Duration, Biofeedback, Motor Power and Pulse Demand. Press the CHECK MARK ('✓') button to select the option. In this example, the DURATION was selected. The following screen will be displayed:

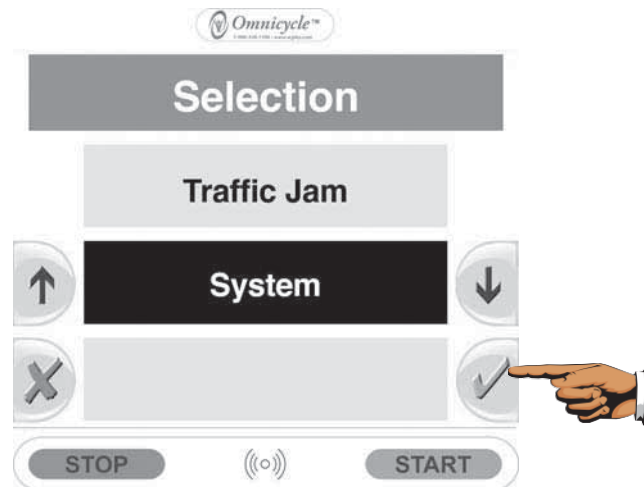


Scroll thru the selections available by pressing the UP or DOWN arrows. Press the CHECK MARK ('✓') button to select the value for that parameter. At this point, that value will be saved, and the screen will display the previous available menu for the Cardio program.

**NOTE:** Pressing the X button will return the user to the previous menu, without making a selection from the current screen.

## Setting user default parameters:

In the example on the previous page, the Cardio program was selected, and a change was made to the duration of the exercise. The user may wish to save this change as the new default setting for the Omnicycle® Elite. Scroll down under the selection screen until you see SYSTEM displayed in black. The following screen will be displayed:



Scroll thru the selections available by pressing the UP or DOWN arrows. Press the CHECK MARK ('1') button to select the SYSTEM parameter. The following screen will be displayed:



Press the CHECK MARK ('1') button to select the SET PARAMS AS DEFAULT to lock the default settings to those that the user has selected.

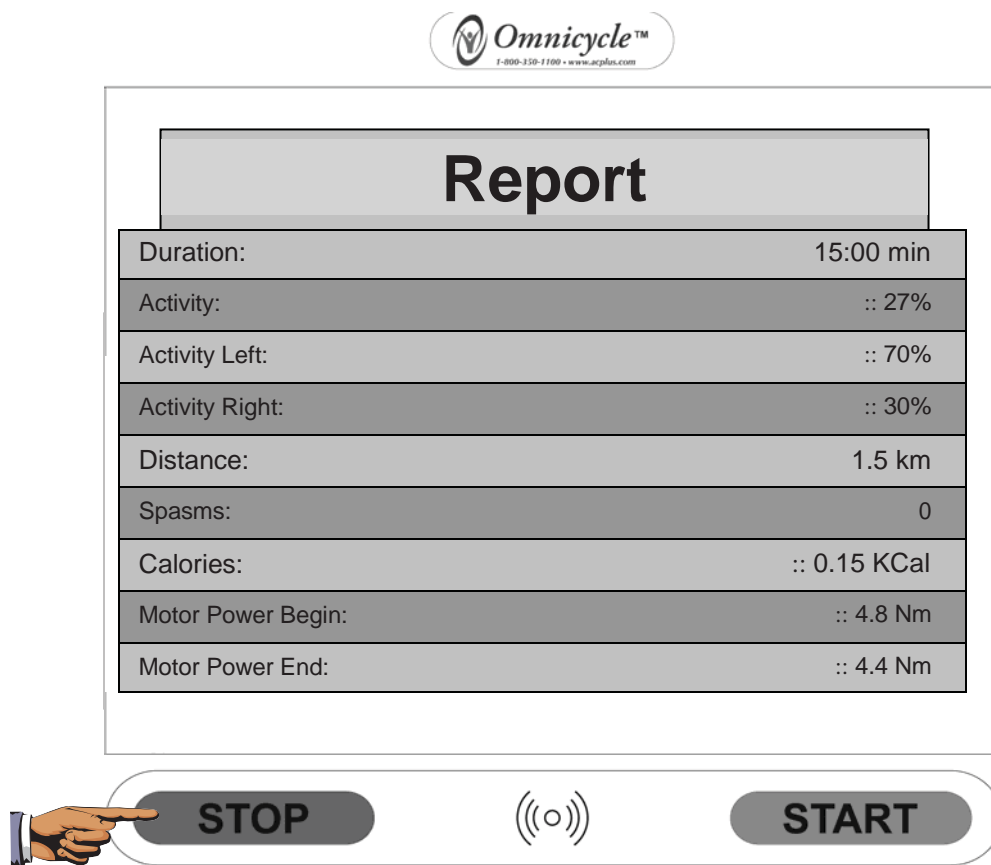
## Reset Factory Default Settings:



The Omnicycle® Elite has a number of exercising programs that are based on the needs of a typical patient group. For each patient group, the exercising parameters can be selected and set on the submenu. The user may also set their default parameters. To return to the factory default parameters, press the STOP button followed by the RESET DEFAULT button and hold both buttons for three (3) seconds. The system will indicate SETTINGS RESTORED.

## Obtaining Exercise Session Analysis

When the STOP button is pressed twice at any time during an exercise session, the exercise session will end, and the display will then show the exercise session analysis data. Also, when the exercise session is completed and the session time expires, the exercise session analysis data is displayed automatically. The following screen will be displayed:



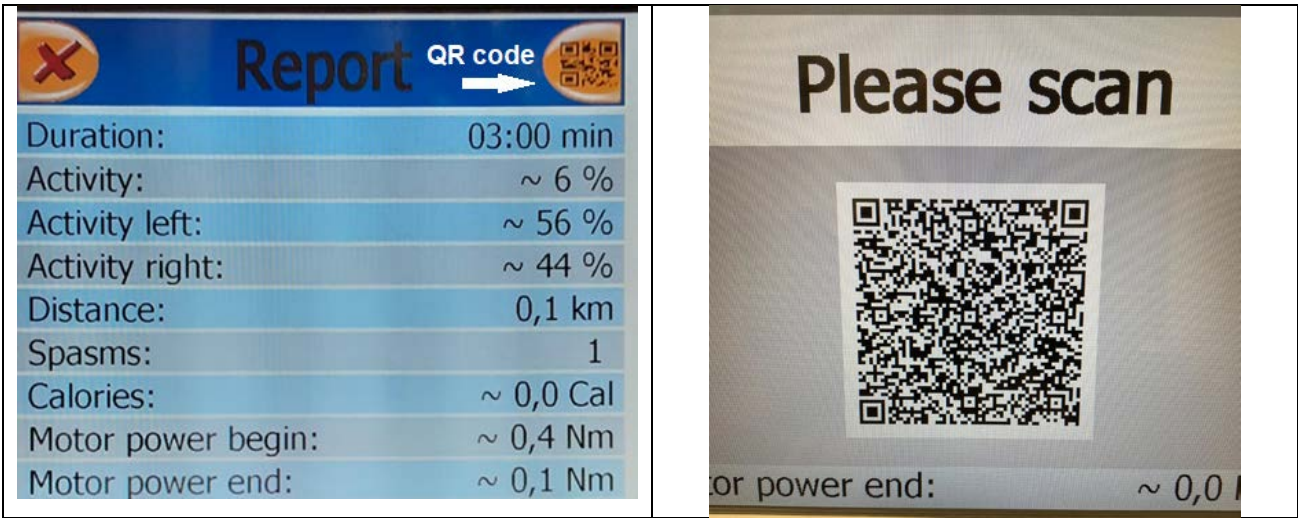
The report may be printed by tapping the screen and following the printer screen options, or by touching the printer icon on the screen.



If display time for this screen ends and the screen reverts to the start-up screen, by pressing the STOP button one time, or by touching the printer icon, you may return to the activity report and be able to reprint the report. The report is only held in memory until the next exercise program has completed one minute of continuous exercise.

End of Treatment: QR CODE

At the end of a treatment session, the Omnicycle exercise report is displayed. The top right corner is an image of a QR code. If you select this, a pop-up window containing a QR code with enabled device information can be scanned using the ACPlus application.



## APPENDIX II – ELECTROMAGNETIC COMPATIBILITY (EMC)

### EMC Notes

- The Omnicycle® Elite is to be used exclusively with the original power cable.
- Only the provided cardio pulse set is to be used with the Omnicycle® Elite. Other pulse sensors might damage or affect the EMC behavior.
- Only the provided Bluetooth® printer is to be used with the Omnicycle® Elite.
- The Omnicycle® Elite should not be used in close proximity with other medical devices.
- The immunity level requirements of IEC 60601 are met.

### Electromagnetic Emissions

Directives and Manufacturing Declaration – Electromagnetic Emissions		
The Omnicycle® Elite is designed for operation in an electromagnetic environment as described below. The customer or the user should make sure that the unit is used in such an environment.		
Emission measurement	Compliance	Directive for electromagnetic environment
HF emissions according to CISPR 11	Group 1	This device uses HF energy exclusively for internal functions. This incurs very low HF emissions so it is unlikely to interfere with any nearby electronic device.
HF emissions according to CISPR 11	Class B	This device is designed for use in all kinds of facilities, including: - Residential buildings - Facilities that are directly connected to a public mains which also supplies residential buildings.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuation/flicker according to IEC 61000-3-3	Met	

### Immunity to Electromagnetic Disturbance

Directives and Manufacturing Declaration – Immunity to Electromagnetic Disturbance			
The Omnicycle® Elite is designed for operation in an electromagnetic environment as described below. The customer or the user should make sure that the unit is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Level of Conformity	Directive for electromagnetic environment
Static Discharge (ESD) IEC 6100-4-2	± 6kV contact discharge (indirect) ± 8kV air discharge	± 6kV contact discharge (indirect) ± 8kV air discharge	Floors should be wooden, concrete or ceramic tiled. If the floor contains synthetic materials, the relative air humidity must be at least 30%.
Fast Transients IEC 61000-4-4	± 2kV for supply lines ± 1kV for inputs/outputs	± 2kV for supply lines ± 1kV for inputs/outputs	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges IEC 61000-4-5	± 1kV differential mode voltage (symmetrical) ± 2kV common mode voltage (asymmetrical)	± 1kV differential mode voltage (symmetrical) ± 2kV common mode voltage (asymmetrical)	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage Dips and Fluctuations IEC 61000-4-11	< 5% U <sub>T</sub> for 0.5 periods (> 95% dip) 40% U <sub>T</sub> for 5 periods (60% dip) 70% U <sub>T</sub> for 25 periods (30% dip) < 5% U <sub>T</sub> for 5 s (>95% dip)	< 5% U <sub>T</sub> for 0.5 periods (> 95% dip) 40% U <sub>T</sub> for 5 periods (60% dip) 70% U <sub>T</sub> for 25 periods (30% dip) < 5% U <sub>T</sub> for 5 s (>95% dip)	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If continuous operation is required, an external non-interruptible power system will be required.

**Note:** U<sub>T</sub> is the supply AC voltage before the test level is applied.



## Immunity to Electromagnetic Disturbance (cont.)

Directives and Manufacturing Declaration – Immunity to Electromagnetic Disturbance			
The Omnicycle® Elite is designed for operation in an electromagnetic environment as described below. The customer or the user should make sure that the unit is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Level of Conformity	Directive for electromagnetic environment
Conducted HF Emissions IEC 61000-4-6	3V <sub>eff</sub> 150kHz to 80 MHz	3V <sub>eff</sub>	Portable and mobile radio equipment should not be used closer to this device than the protective distance recommended. The equation for the transmission frequency in questions is used to calculate it. Recommended protective distance: $d = [3.5/3] * '1P = 1.17 * '1P$ $d = [3.5/3] * '1P = 1.17 * '1P$ for 80MHz to 800MHz $d = [3.5/3] * '1P = 2.33 * '1P$ for 800MHz to 2.5GHz  with (P) as the transmitters power rating in watts (W) according to the indications of the transmitter manufacturer and (d) as the recommended protective distance in meters (m)
Radiated HF Emissions IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	

**Note:** For 80MHz and 800MHz, the higher frequency range applies.

These guidelines may not be applicable in every case. Buildings, objects and persons influence the propagation of electromagnetic waves by absorption and reflection. An exact technical estimate of the field intensity of stationary transmitters such as base stations of mobile phones and land mobile radio devices, amateur radio stations, AM and FM radio broadcast and TV stations is not possible.

## Recommended Protective Distances

The Omnicycle® Elite is designed for operation in an electromagnetic environment as described below. The customer or the user of the Omnicycle® Elite can help prevent electromagnetic disturbances by observing the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the Omnicycle Elite as indicated below (depending on the output power of the telecommunication device).

Power rating of transmitter [W]	Protective distance depending on transmission frequency [m]		
	150KHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
	$d = 1.17 \sqrt{P}$	$d = 1.17 \sqrt{P}$	$d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.30

The distance for any transmitters the nominal power of which is not indicated in the table above can be determined by means of the equation given. P is the nominal power of the transmitter in Watts (W) as indicated by the transmitter manufacturer.

### Note 1:

An additional factor 10/3 was used for calculating the recommended protective distance for transmitters in the frequency range between 80 MHz and 2.5 GHz. This reduces the probability of a mobile/portable communication device that was brought to the user area by mistake causing a disturbance.

### Note 2:

These guidelines may not be applicable in every case. Buildings, objects and persons influence the propagation of electromagnetic waves by absorption and reflection.