

MyoCycle vs. RT300

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Table 1: Information regarding the characteristics of the MyoCycle MC-2 and RT300 FES bikes.

Characteristics	MyoCycle MC-2	RT300
Clinical Characteristics		
Intended for prescription or over-the-counter use?	Prescription only	Prescription only
Intended medical indication (indications for use / medical purpose)	The MyoCycle is intended for general rehabilitation for: 1. Muscle re-education 2. Relaxation of muscle spasms 3. Prevention or retardation of disuse atrophy 4. Increasing local blood circulation 5. Maintaining or increasing range of motion	RT300 is intended to be used for the following. 1. Muscle re-education 2. Relaxation of muscle spasms 3. Prevention or retardation of disuse atrophy 4. Increasing local blood circulation 5. Maintaining or increasing range of motion
Intended patient population	Patients with weak or paralyzed leg or core muscles, likely resulting from neurological injury or illness (e.g., spinal cord injury, multiple sclerosis, stroke, brain injury, cerebral palsy), ages 12 and older	Patients with weak or paralyzed leg or core muscles, likely resulting from neurological injury or illness (e.g., spinal cord injury, multiple sclerosis, stroke, brain injury, cerebral palsy), ages 4 and older (pediatric version) or 12 and older (adult version)
Muscles (sites) intended for stimulation	Bilateral quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, abdominals, erector spinae	Bilateral quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, abdominals, erector spinae (RT300-SL); shoulder, biceps, triceps, anterior, posterior and middle deltoid, wrist, grasp (wrist and finger flexors and extensors) (RT300-SLSA)
Unilateral or bilateral stimulation	Uses bilateral or unilateral stimulation.	Uses bilateral or unilateral stimulation.
Operating principle	Wheelchair accessible stationary cycling ergometer equipped with electric motor for pedaling assistance and resistance and a nerve stimulator to facilitate active muscle contractions in the lower body. Leg cycling with coordinated muscle stimulation produces clinical effects.	Wheelchair accessible stationary cycling ergometer equipped with electric motor for pedaling assistance and resistance and a nerve stimulator to facilitate active muscle contractions in the lower body. Leg or arm cycling with coordinated muscle stimulation produces clinical effects.

Characteristics	MyoCycle MC-2	RT300
Seating	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer. Includes chair restraints.	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer. Includes chair restraints.
Passive cycling	Uses motor to provide assistance during passive cycling	Uses motor to provide assistance during passive cycling
Motorized arm crank	Legs only—no arm crank	Legs or arm cycling with RT300-SLSA
Pulse oximeter / heart rate monitor interface	Utilize compatible BLE heart rate monitor data for display and recording. No pulse oximeter interface and no alarm.	Utilize pulse and SpO2 data for display, recording and alarming
Virtual reality cycling	<u>Compatible with Zwift</u> and other virtual reality cycling applications using BLE.	Not compatible with third-party virtual reality cycling applications.
Technical Characteristics		
Software	Uses embedded microcontrollers running custom software with an Android OS interface	Uses embedded microcontrollers running custom software with a Windows OS interface
Stimulator	0-140 mA 10 channel charge balanced stimulator. Optionally, the device can accommodate two 3-channel patient cables for a total of 6 channels or two 5-channel patient cables for a total of 10 channels.	0-140 mA 6 channel charge balanced stimulator. Optionally, the device can accommodate two 6-channel stimulators for a total of 12 channels.
Stimulation channels	Up to 10 channels	Up to 12 channels
Flywheel	Uses electric motor to create flywheel effect with reduced weight and space	Uses electric motor to create flywheel effect with reduced weight and space
Touchscreen interface	Uses a 10-inch touchscreen graphical user interface	Uses a 10-inch touchscreen graphical user interface
Wireless communications	Utilizes an integrated 802.11 a/b/g/n/ac WLAN (Wi-Fi), Bluetooth, and Bluetooth Low Energy (BLE) module	Utilizes a 802.11 a/b/g/n WLAN (Wi-Fi) module and multiple Bluetooth modules
Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs.	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs.
Power source	100-240 VAC, 50-60 Hz	115-230 VAC, 50-60 Hz

Characteristics	MyoCycle MC-2	RT300
Electrical safety	Complies with IEC 60601-1 (class II equipment), IEC 60601-1-11, and IEC 60601-2-10	Complies with IEC 60601-1 (class II equipment), IEC 60601-1-11, and IEC 60601-2-10
Electromagnetic compatibility	Complies with IEC 60601-1, IEC 60601-1-2 (class B equipment), and IEC 60601-1-11	Complies with IEC 60601-1, IEC 60601-1-2 (class B equipment), and IEC 60601-1-11
Regulated current or voltage?	Constant current	Constant current
Timer range	60 minutes	60 minutes
Weight	110 lbs (50 kg)	85 lbs (39 kg)
Size	Length: 35" (89 cm) Width: 27.5" (70 cm) Height: 44"-52.5" (112-133 cm)	Length: 31.5" (80 cm) Width: 19.3" (49 cm) Height: 36.2"-40.6" (92-103 cm)
Key materials	Aluminum, powder-coated steel; ABS, PC, and PLA plastic; electronics	Aluminum, powder-coated steel; polystyrol; polyurethane; electronics
Output waveform	Biphasic, symmetric, charge-balanced, rectangular pulses with 100 μ s phase interval	Alternating monophasic, symmetric, charge-balanced, rectangular pulses
Maximum output voltage	180 VDC	200 VDC
Maximum output current	140 mA	140 mA
Maximum phase duration	500 μ s (1,100 μ s maximum biphasic pulse duration)	500 μ s (up to 3,000 μ s for use in clinic with lower motor neuron damage)
Maximum pulse frequency	100 Hz	100 Hz
Maximum phase charge	70 μ C	70 μ C
Maximum current density	3.6 mA/cm ² (500 Ω load with provided electrodes)	3.6 mA/cm ² (500 Ω load with provided electrodes)
Maximum power density	0.025 W/cm ² (500 Ω load with provided electrodes)	0.025 W/cm ² (500 Ω load with provided electrodes)
Conditions for use	Temperature: 5°C to 40 °C (41°F to 104 °F) Relative humidity: 15% to 90%, non-condensing Atmospheric pressure: 700 hPa to 1,060 hPa Altitude: $\leq$ 5,000 m (16,400 ft)	Temperature: 5°C to 25 °C (41°F to 73 °F) Relative humidity: 45% to 75%, non-condensing Atmospheric pressure: 86 hPa to 1,060 hPa Altitude: $\leq$ 3,000 m (10,000 ft)

Characteristics	MyoCycle MC-2	RT300
Biological Characteristics		
Materials intended for contact with human tissues	Only intended for contact with intact, healthy skin <u>Stimulation electrodes:</u> MultiStick® adhesive hydrogel from Axelgaard Manufacturing Co. Ltd. Has passed ISO 10993-1 requirements for skin contact, demonstrating no cytotoxicity, no irritation, and no sensitization upon skin contact. <u>Orthotic pedal calf support:</u> Healthcare seating and positioning fabric (Herculite Products, Inc.).	Only intended for contact with intact, healthy skin <u>Stimulation electrodes:</u> MultiStick® adhesive hydrogel from Axelgaard Manufacturing Co. Ltd. Has passed ISO 10993-1 requirements for skin contact, demonstrating no cytotoxicity, no irritation, and no sensitization upon skin contact. <u>Orthotic pedal calf support:</u> Healthcare seating and positioning fabric (details unknown).