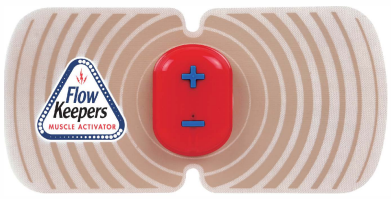
FlowKeepers®

They keep your muscles moving .... when you aren't

User's Guide



FlowKeepers®

Congratulations on your purchase of FlowKeepers® ! This innovative product promotes blood flow in your legs by contracting your muscles and has been cleared by the FDA.

How does FlowKeepers® work?
This device "mimics nature." It is uniquely programmed to activate the calf muscles, which is perceived by the user as a muscle movement. This device is the result of 20 years of research and development and was invented by a world-renowned neurophysiologist.

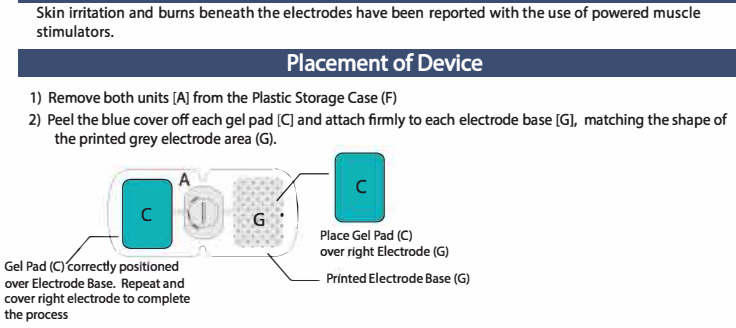
How to use and wear your FlowKeepers®
FlowKeepers® is convenient and easy-to-use. Each unit is constructed similar to a "butterfly" design, with one wing on either side of a battery powered control unit. The butterfly measures 2.75 inches x 5.5 inches (height x length) and weighs less than one ounce.

The underside of each wing has a printed pattern onto which adhesive gel pads (electrodes) are placed. These gel pads conduct electrical energy to each leg and the gel pad's adhesive properties keep the device attached to your leg to deliver the electric pulse. Each unit should be worn separately, with one device attached to each calf or leg muscle behind the knee. FlowKeepers® can be worn under loose pants and is meant to be applied directly on the skin. The gel pads act as electrodes and are clear, hypoallergenic rectangles. Remove them from your legs slowly and with caution, as they may tear if too much force is applied in removing them.

Package Contents

Each FlowKeepers® box contains the following items:

(A) 2 - FlowKeepers® units w/ butterfly wings, control unit and LED diodes
(B) 2 - CR2032Li Lithium Batteries
(C) 1 - Gel Pad Envelope (holds 8 gel pads, two per poly bag) replacements are available from your retailer or at www.flowkeepers.com
(D) 1 - Paper Storage Board (Blue) - to be used to mount ea. FlowKeepers® unit when not in use
(E) 1 - Instruction Sheet
(F) 1 - Plastic Storage Case - which holds all items inside the storage box when not in use (T) 1 - Gel Pad Envelope
(U) 1 - Battery removal tool



Application Instructions

FlowKeepers® should not be used on any part of the body other than the calf muscles. It should not be used by children, during pregnancy or in any of the following conditions:

- If you have broken, infected, inflamed or irritated skin at the attachment site.
- If you have blood clots in your legs, or if either of your legs are warm, achy, swollen or red.
- If you have a pacemaker, an internal defibrillator or congestive heart failure.
- If you have any known allergy to electrode gels.
- If you are not sure about the aforementioned conditions or have any additional concerns, consult your physician.

Indications for Use

1) To temporarily increase local blood circulation in healthy leg muscles
2) To stimulate muscles in order to improve and facilitate muscle performance
3) For temporary relief of pain associated with sore and aching muscles of the lower extremities (legs) due to strain from exercise or normal household or work activities.

Contraindications

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

Warnings

1) The long-term effects of chronic electrical stimulation are unknown.
2) Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3) Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4) Stimulation should not be applied transthoracically, in that the introduction of electrical current into the heart may cause arrhythmias.
5) Stimulation should not be applied trans-cerebrally.
6) Stimulation should not be applied over swollen, infected or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
7) Stimulation should not be applied over, or in proximity to, cancerous lesions.

Precautions

1) Safety of powered muscle stimulators for use during pregnancy has not been established.
2) Caution should be used for patients with suspected or diagnosed heart problems.
3) Caution should be used for patients with suspected or diagnosed epilepsy.
4) Caution should be used in the presence of the following:
   - When there is a tendency to hemorrhage following acute trauma or fracture
   - Following recent surgical procedures when muscle contraction may disrupt the healing process
   - Over the menstruating or pregnant uterus
   - Over areas of the skin which lack normal sensation.
5) Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
6) Electrode placement and stimulation settings should be applied according to the included manufacturer's directions or the guidance of your practitioner.
7) Powered muscle stimulators should be kept out of the reach of children
8) Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
9) Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

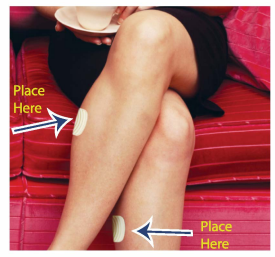
Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

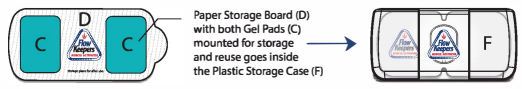
Placement of Device

1) Remove both units [A] from the Plastic Storage Case (F)
2) Peel the blue cover off each gel pad [C] and attach firmly to each electrode base [G], matching the shape of the printed grey electrode area (G).

3) Remove the clear film and attach the unit to your calf muscle, behind the shin so that the wings of the "butterfly" will adhere to the widest part of the muscle as illustrated, with the [+] button and logo facing upwards. Place one of the FlowKeeper® units (A) on the left calf first, (right hand users) and then place the other unit (A) on the right calf. See the back side of this Instruction Sheet (E) for further details.

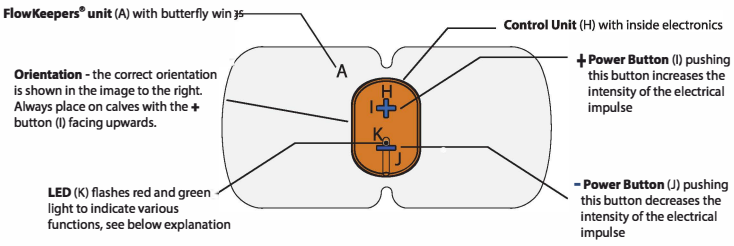


4) **NOTE:** after each use place both FlowKeeper® units (A) on the Paper Storage Board (D) with the Gel Pads attached (C). Then place the Storage Board (D) with both FlowKeeper® devices attached inside the Plastic Storage Case (F) until the next use of the device, see drawing below. Note, that the Gel Pads (C) can be re-applied to skin more than 10 times with normal use and proper storage.



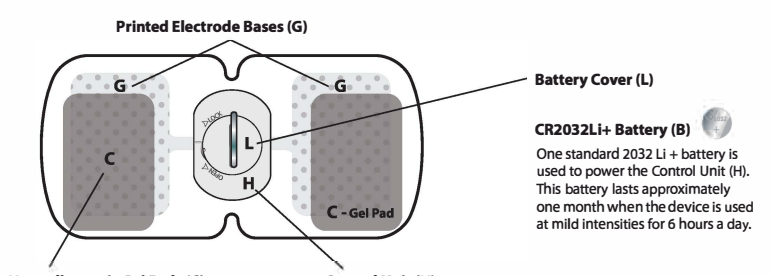
FlowKeepers® Unit - General Description

FRONT VIEW



Description: the Control Unit (H) has blue [+,-] power buttons on it's surface. The Control Unit (H) generates electrical impulses which are delivered to your skin via the printed Electrode Bases (G) on the underside of the FlowKeepers® unit (A) when the attached Gel Pads (C) cover each Electrode Base (G). A LED light (K) is situated right above the minus Power Button (J). This LED flashes with a green light continuously, once each second, when the device is in use and beeps when the intensity of the impulse is increased or decreased using the Power Buttons (I & J). When the battery power is low it changes to a red light. Additionally, the LED (K) will flash red and beeps twice when the Control Unit (H) reaches it's lowest or highest output. When the Gel Pads (C) are unattached from the FlowKeepers® unit (A) , or when there is poor contact with the skin, the LED will flash green and beep continuously.

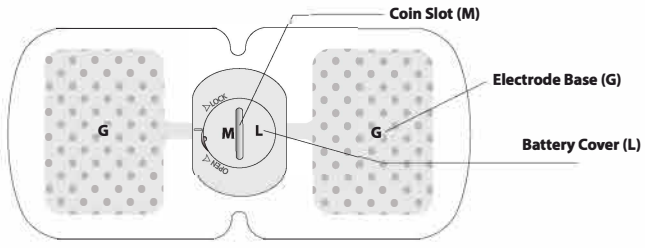
FlowKeepers® Unit - General Description 2



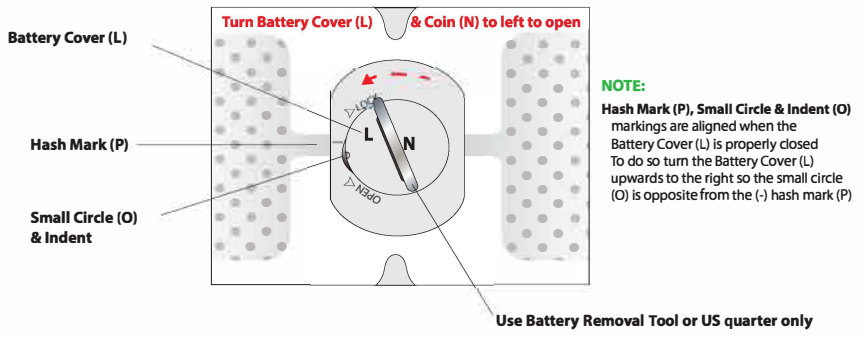
The Gel Pads are attached to the underside of the Electrode Bases (G) so they are fully covered. Each Gel Pad (C) acts to conduct the electrical impluses from the Control Unit (H) to your skin. They measure 2.5" x 3.25" inches, (width x length) and have a laminated film on each side. One side has clear film and the other side has blue film. The blue side has stronger adhesion and is applied to the Electrode Bases (G) first before removing the clear film. After completing this you can remove the clear film when you are ready to attach the FlowKeepers® unit (A) to your leg. Note, that your FlowKeepers® units come with two sets of Gel Pads (C) so you have an extra pair on hand. Extra Gel Pads can then be purchased separately from your retailer or online at **www.flowkeepers.com**

How to insert and remove the Battery

1) Locate the Battery Cover (L) and Coin Slot (M) - on the underside of the FlowKeepers® unit (A)

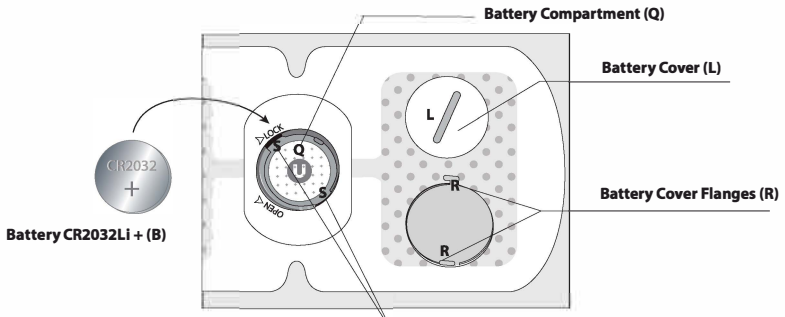


2) How to open the Battery Compartment (Q) - press the edge of the battery removal tool or a US Quarter fiBattery Cover (L) is ready to be opened. Do not force the Coin Slot (M) beyond this point or you can damage rmly into the Coin Slot (M) and turn counterclockwise to the left. You will hear a click when the the plastic and coin slot on the Battery Cover (L) making it difficult to open and close.



NOTE:
Hash Mark (P), Small Circle & Indent (O) markings are aligned when the Battery Cover (L) is properly closed To do so turn the Battery Cover (L) upwards to the right so the small circle (O) is opposite from the (-) hash mark (P)

3) How to insert the Battery (B) - open the Battery Cover (L) and insert the CR2032Li + battery (B) in the battery compartment (Q) with the + symbol facing up.



4) How to close the Battery Compartment (Q)

insert the battery cover flanges (R) into the battery compartment notches (5). Insert a the battery removal tool or a US Quarter into the coin slot (M) and turn clockwise so the coin slot is in the vertical position. The battery compartment and cover are now locked in place. See the drawing above for further information.

Instructions for Use

Turning on your Flowkeepers® device

1) After the FlowKeepers® is in position (see Placement of Device section), push the [+] power button for 3 seconds, (or until it flashes green and a "beep" sounds) and then release. After sending 5 electrical impulses at 1 second intervals, the LED diode will start flashing green at 1 second intervals and will then deliver a pulse every 10 seconds. You will not feel a muscle 'twitch' at this point, because the starting voltage is at it's lowest setting.
2) Continue to press the [+] button to increase the voltage intensity. Each time the button is pressed, 5 pulses will be delivered over 5 seconds and then a regular cycle of 1 stimulus every 10 seconds will continue. As you increase the intensity, you will feel a tiny twitch that will grow stronger until you see muscle movement. This usually occurs after 5 button pushes. If the twitch is too strong or uncomfortable, push the [-] button, until desired intensity is reached.
3) FlowKeepers® functions effectively only when there is a visible muscle movement. After ~10 minutes of use, the electrode conduction improves and less current is needed to produce the same muscle movement resulting in stronger muscle contraction. You may then reduce the intensity by pushing the [-] button to reduce the muscle movement to a comfortable level.
4) Repeat steps 1, 2, & 3 with the second unit.

Turning your Flowkeepers® device off

1) To turn off, press and hold the [-] button for three seconds, (or until it flashes green and a "beep" sounds) and release.
2) Repeat step 1 with the second unit.
3) Remove both units from your calf muscles and store after placing the Gel Pad (C) side that is facing out against the Paper Storage Board (D) for safekeeping until it's next use.
4) **Note:** Flowkeepers® devices are programmed to shut off automatically after 10 hours of use. If disconnected while in use, your FlowKeepers® Will beep, flash a green light and shut itself off after 2 minutes.

Usage and Storage Tips

- The Gel Pads (C) included with this device can be used repeatedly. Frequent use or excessive skin debris will affect your FlowKeepers®output. If this occurs replace with new Gel Pads from this box or replacement Gel Pads that you can buy separately at retail or online at www.flowkeepers.com
- This device is partially constructed of soft materials which can be damaged if pulled or impacted. When storing lay flat and do not fold.
- If the two Gel Pads (C) do not have good contact with your skin the device will start beeping and flashing green. If this occurs, re-adhere the Gel Pads firmly to your skin. You can try placing them in a slightly different location nearby for better adhesion. If the Gel Pads are still not adhering to your skin, remove them by peeling them off your FlowKeepers® device and rolling them into a ball so they can be disposed of. Then replace with new set of Gel Pads as described above.
- **Note: This device cannot be immersed in water!** Always maintain a clean seal and housing.
- This device should be stored at a temperature between -10°c and + 60°c, with a relative humidity ranging from 10 to 85%. Always store in a well-ventilated room and prohibit direct exposure to sunlight. Do not store with or near toxic, harmful or corrosive substances.
- **This device is not suitable for children and is only intended for adults (individuals of 18 years or older).**

⚠ WARNING

- **INGESTION HAZARD**: This product contains a button cell or coin battery.
- **DEATH** or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours.**
- KEEP new and used batterles **OUT OF REACH OF CHILDREN**
- **Seek immediate medical attention** if a battery is suspected to be Swallowed or inserted inside any part of the body

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Hockessin, DE 19707, USA
www.flowkeepers.com
1-302-388-5016

Designed and developed in USA
Made in China

US Patents:5,643 331; 6,002,965; 6,432,240
FlowKeepers® is a registered TM of Krenerb, LLC

External dimensions:
L: 140.60 mm x W:67.14 mm x H: 10.50 mm

- **is cleared for use by the FDA**

Electromagnetic Safety - Information Tables

Tables 1,2,4 and 6 from IEC 60601-1-2 for FlowKeepers®

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS

Guidance and Manufacturer's declaration – electromagnetic emissions		
The FlowKeepers®device is intended for use in the electromagnetic environment specified below. The customer or the user of the FlowKeepers device should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The FlowKeepers®device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 Harmonic emissions Voltage fluctuations/ flicker emissions	Class B N/A; battery powered N/A ; battery powered	The FlowKeepers®device is **not suitable for use in hospital environments** but is suitable for use in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The FlowKeepers®device is intended for use in the electromagnetic environment specified below. The customer or the user of the FlowKeepers®device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air± 8kV air	Air: ±8 kV Contact: ±6 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.[(a)] The FlowKeepers®device is MR UNSAFE. Remove the FlowKeepers®device before an MRI procedure. 

Table 4 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The FlowKeepers®device is intended for use in the electromagnetic environment specified below. The customer or the user of the FlowKeepers®device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	N/A [V_1]	Portable and mobile RF communications equipment should be used no closer to any part of the FlowKeepers®device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance: $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum power output of the transmitter in watis (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m [E_1] 80 MHz to 2.5 GHz	

Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the FlowKeepers®device			
The FlowKeepers®device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the FlowKeepers®device can help prevent electromagnetic interference by maintaining a minimum distance (meters) between portable and mobile RF communications equipment (transmitters) and the FlowKeepers®device as recommended below, according to the maximum output power (watts) of the transmitter.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d=[\frac{3.5}{E_1}]\sqrt{P}$ **d = 1.17** $\sqrt{P}$	**800 MHz to 2.5 GHz** $d=[\frac{7}{E_1}]\sqrt{P}$ **d = 2.33** $\sqrt{P}$
0.01	N/A	0.12	0.23
0.1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE: For 1W RFID transmitters, the recommended separation distance is 2.3 meters. NOTE: At 800 MHz, the separation distance for the higher frequency range applies. NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			