

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

)	
)	
WESTERN CLINICAL ENGINEERING)	
LTD.,)	
)	
Plaintiff,)	Civil Action No. _____
v.)	
)	JURY TRIAL DEMANDED
SMART TOOLS PLUS, LLC,)	
)	
Defendants.)	
)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Western Clinical Engineering Ltd. (“WCE” or “Plaintiff”), by and through its attorneys, hereby brings this Complaint for patent infringement against Defendant Smart Tools Plus LLC (“STP” or “Defendant”) and alleges as follows. The allegations herein are made based on personal knowledge as to Plaintiff with respect to its own actions and upon information and belief as to all others.

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and for such other relief as the Court deems just and proper. Plaintiff’s claims are based on Defendant’s infringement of U.S. Patent No. RE50,013 (“the ‘013 patent”) and U.S. Patent No. 10,646,231 (“the ‘231 patent”) (collectively, “Patents in Suit”). A true and correct copy of the ‘013 patent is attached hereto as **Exhibit A**. A true and correct copy of the ‘231 patent is attached hereto as **Exhibit B**.

THE PARTIES

2. Plaintiff WCE is a foreign company organized and existing under the laws of Canada, with its principal place of business at #207 1099 W 8th Ave, Vancouver, BC, Canada, V6H 1C3.

3. Upon information and belief, Defendant STP is a limited liability company organized and existing under the laws of Ohio and has a principal place of business at 20636 Castlemaine Circle, Strongsville, Ohio 44149.

4. Upon information and belief, Defendant STP may be served through its registered agent, Timothy A. Boyko, 7393 Broadview Road, Suite A, Seven Hills, Ohio 44131.

JURISDICTION AND VENUE

5. This is an action for patent infringement in violation of the Patent Act of the United States, 35 U.S.C. §§ 1 *et seq.*

6. This Court has original and exclusive subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Patent Laws of the United States, 35 U.S.C. § 1 *et. seq.*

7. This Court has personal jurisdiction over Defendant because Defendant is incorporated in Ohio and has its principal place of business in Ohio and in this District. On information and belief, Defendant has transacted and is continuing to transact business in this District that includes, but is not limited to, committing acts of patent infringement giving rise to this action by use and sale of products and systems that practice the subject matter claimed in the Patents in Suit involved in this action.

8. Venue is proper in this District under 28 U.S.C. § 1400(b) because Defendant resides in Ohio and in this District. On information and belief, Defendant has a regular and

established place of business in this District and has committed acts of infringement in this District.

BACKGROUND

9. Plaintiff WCE is a biomedical engineering research and development company that specializes in tourniquet technologies for blood flow restriction (“BFR”), elective surgeries, emergencies, and other novel applications. BFR is a technique that combines low intensity exercise with blood flow restriction, which has been found to increase strength, performance, and recovery of patients such as individuals undergoing rehabilitation, athletes, and the elderly. WCE holds patents and other intellectual property, including the Patents in Suit, related to products that are marketed and sold through WCE’s licensee, Delfi Medical Innovations Inc. (“Delfi”).

10. One of Plaintiff’s most successful innovations is the PTS Personalized Tourniquet System for BFR (“PTS System”), designed to safely control tourniquet pressure for BFR applications. Plaintiff’s PTS System provides BFR via an inflated tourniquet cuff that is applied to a patient’s limb, which restricts blood flow in the limb. The PTS System ensures blood flow is restricted, not occluded, by measuring the patient’s limb occlusion pressure (“LOP”) and/or distal occlusion pressure (“DOP”) and setting a pressure according to the patient’s LOP/DOP. Using Plaintiff’s innovative PTS System, patients working at low intensity and load can achieve similar benefits as if they were working at high intensity and load, reducing stress on the patient’s body and minimizing the risk of injury to the patient. An image of Plaintiff’s PTS System is provided below as Figure 1.



**Figure 1
(The PTS System)**

11. The '013 patent, entitled "Tourniquet System for Personalized Restriction of Blood Flow," was duly and lawfully issued by the U.S. Patent and Trademark Office on June 18, 2024. WCE is the current owner of all rights, title, and interest in the '013 patent.

12. The '013 patent is generally directed to a system for controlling tourniquet cuff pressure to restrict blood flow penetration past the cuff based on a personalized restrictive pressure ("PRP"), which is a restrictive pressure based on LOP.

13. The '231 patent, entitled "Personalized Tourniquet for Intermittent Vascular Occlusion," was duly and lawfully issued by the U.S. Patent and Trademark Office on May 12, 2020. WCE is the current owner of all rights, title, and interest in the '231 patent.

14. The '231 patent is generally directed to an apparatus for intermittent vascular occlusion based on a personalized tourniquet pressure ("PTP"), which is a restrictive pressure based on DOP.

15. Plaintiff has sought to protect its intellectual property with patents such as the Patents in Suit. For example, the PTS System is associated with the '013 and '231 patents on the

website of WCE’s licensee, Delfi. See <https://www.delfimedical.com/patents/> (last accessed November 5, 2024).

16. This patent infringement action arises because of Defendant’s use, sale, and offer for sale of various BFR products marketed under the name SmartCuffs® to customers in the United States. For example, on information and belief, Defendant distributes and sells BFR products, including but not limited to the SmartCuffs® 4.0, SmartCuffs® 3.0 Pro, and SmartCuffs® 3.0 (collectively, “the Accused Products”), that infringe one or more claims of the Patents in Suit. See, e.g., <https://www.smarttoolsplus.com/smartcuffs/products/> (last accessed November 5, 2024). Images of the Accused Products are provided below as Figure 2 (SmartCuffs® 4.0), Figure 3 (SmartCuffs® 3.0 Pro), and Figure 4 (SmartCuffs® 3.0).



Figure 2
(SmartCuffs® 4.0)



Figure 3
(SmartCuffs® 3.0 Pro)



Figure 4
(SmartCuffs[®] 3.0)

17. On September 23, 2021, counsel for Plaintiff wrote to Defendant to provide notice that Defendant’s SmartCuffs[®] 3.0 Pro and SmartCuffs[®] 3.0 infringe the ‘231 patent and U.S. Patent No. 10,646,232 (“the ‘232 patent”), which reissued as the ‘013 patent.

18. Following various communications and exchanges of information between counsel for the parties, Defendant indicated that it would redesign the SmartCuffs[®] 3.0 Pro to disable or remove the Ischemic Preconditioning Mode (“IPC Mode”) and the Autoregulation Mode.

19. In August 2022, the parties reached a limited settlement agreement related to sales by Defendant of the SmartCuffs[®] 3.0 Pro during the period from September 23, 2021 to November 7, 2022. The agreement was limited to the SmartCuffs[®] 3.0 Pro with Autoregulation Mode, but the parties agreed that they had no agreement and made no covenants with respect to the SmartCuffs[®] 3.0 or any SmartCuffs[®] 3.0 Pro model without Autoregulation Mode.

20. Subsequent to the parties’ agreement, Defendant has continued to make, use, sell, offer for sale, and/or import the SmartCuffs[®] 3.0.

21. Subsequent to the parties' agreement, Defendant has continued to make, use, sell, offer for sale, and/or import the SmartCuffs[®] 3.0 Pro. Despite the parties' agreement, Defendant has not disabled or removed the IPC Mode in the SmartCuffs[®] 3.0 Pro.

22. Subsequent to the parties' agreement, Defendant began to make, use, sell, offer for sale, and/or import the SmartCuffs[®] 4.0 in approximately May 2023. The SmartCuffs[®] 4.0 includes an "Intermittent" Mode in which the cuff "inflates during sets and deflates during rest periods."

COUNT I: INFRINGEMENT OF U.S. PATENT NO. RE50,013

23. Plaintiff incorporates by reference the allegations in Paragraphs 1-22 of this Complaint as if fully set forth herein.

24. The '013 patent is in effect and is presumed valid under the Patent Laws of the United States.

25. On information and belief, Defendant has infringed and is infringing at least one claim of the '013 patent under 35 U.S.C. §271 by making (or having made), using, offering for sale, selling, and/or importing in the United States, without authority, the Accused Products including the SmartCuffs[®] 4.0, SmartCuffs[®] 3.0 Pro, and SmartCuffs[®] 3.0.

26. Claim 1 of the '013 patent recites as follows:

Apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on a personalized restrictive pressure (PRP), comprising:

a dual-purpose tourniquet cuff having a single inflatable bladder adapted to encircle a limb;

a controller selectively operating the inflatable bladder of the dual-purpose tourniquet cuff and executing instruction to control:

a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for measuring pressure pulsations

to characterize a limb occlusion pressure (LOP), thereby to identify a minimum pressure at which arterial blood penetration past the cuff is stopped;

a PRP estimator responsive to the sensor module for producing an estimate of a PRP, wherein the estimate of the PRP is less than the LOP and indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff; and

an effector module communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for maintaining pressure in the inflatable bladder near the PRP, thereby restricting but not stopping arterial blood penetration past the cuff.

27. Claim 14 of the '013 patent recites as follows:

An apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on a personalized restrictive pressure (PRP), comprising:

a dual-purpose tourniquet cuff having a single inflatable bladder adapted to encircle a limb;

a controller selectively operating the inflatable bladder of the dual-purpose tourniquet cuff, the controller executing instructions to control:


a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for measuring pressure pulsations to characterize a limb occlusion pressure (LOP), thereby to identify a minimum pressure at which arterial blood penetration past the cuff is stopped; and

a PRP estimator responsive to the sensor module for producing an estimate of a PRP, wherein the estimate of the PRP is less than the LOP and indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.


28. On information and belief, Defendant has made, used, imported, sold, and/or offered to sell the SmartCuffs[®] 4.0. The claim chart below shows how at least independent claims 1 and 14 of the '013 patent read on the SmartCuffs[®] 4.0, based on information currently available to Plaintiff and their attorneys. This claim chart is not intended to limit the scope of

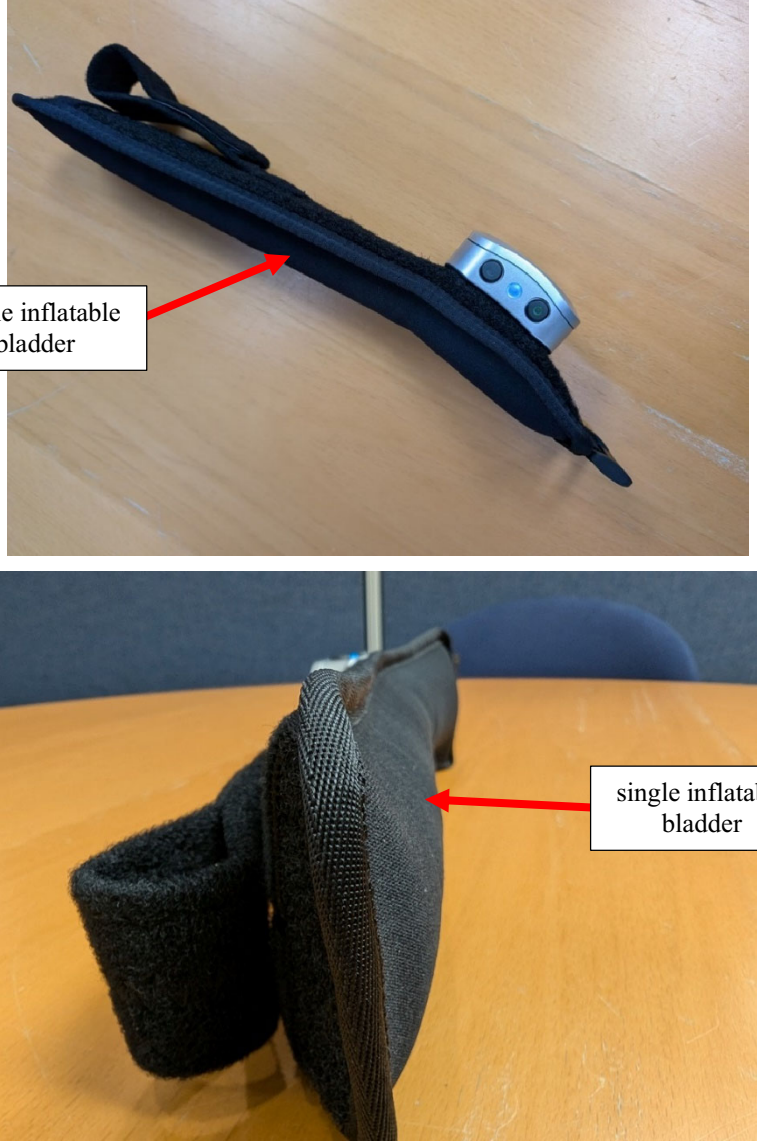
Plaintiff's infringement claim in any way and is intended to be without prejudice to Plaintiff's ability to assert different or additional claims of the '013 patent against Defendant and/or to apply such claims to the SmartCuffs® 4.0 differently in view of additional information that Plaintiff and their attorneys may acquire during the course of this litigation.



29. The SmartCuffs® 4.0 meets each element of claims 1 and 14 of the '013 patent:

Claims of the '013 Patent	SmartCuffs® 4.0
Claim 1	
1. Apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on a personalized restrictive pressure (PRP), comprising:	<p><i>SmartCuffs 4.0 is an apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff.</i></p>  <p>See https://www.smarttoolsplus.com/smartcuffs/products/ (last accessed November 5, 2024).</p>

Claims of the '013 Patent	SmartCuffs® 4.0
	<p>What is Blood Flow Restriction Training?</p> <p>To improve muscular strength and size it has been assumed heavy loads must be lifted. Unfortunately, in certain populations, like older individuals, post-operative patients, or those rehabilitating an injury, high-load exercises can cause injury and not be tolerated.</p> <p>Blood Flow Restriction (BFR) training is a technique in which combines low-intensity exercise under reduced arterial flow conditions. BFR is quantifiably and objectively reducing the amount of blood flow into an extremity by using a specially made medical tourniquet. BFR allows individuals to use low loads yet achieve results similar to high intensity training.</p> <p>Blood Flow Restriction (BFR) Training</p> <p>BFR training was initially developed in the 1960s in Japan and known as KAATSU training.¹</p> <p>Â BFR involves the application of a pneumatic cuff (tourniquet) to the upper arms or the upper legs. BFR can be applied to either one or two of the upper or lower extremities at a time but never all four limbs at one time. <u>The cuff is then inflated to a specific pressure with the aim of obtaining partial arterial restriction and complete venous occlusion.</u> The client is then asked to perform resistance exercises at a low intensity of 20-30% of 1 repetition max (1RM), with high repetitions per set (15-30) and short rest intervals between sets (30 seconds). (2) There are non-exercising protocols for bone healing, recovery and high intensity exercise preparation.Â For example, for bicep curls one can use very light dumbbells (like 2.5 or 5lb weights) with the cuffs and still gain strength and size.Â</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p> <p><i>SmartCuffs 4.0 provides personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on personalized restrictive pressure (PRP).</i></p> <p>After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. <u>This 4.0 model, with its AI-powered processor and proprietary LOP algorithms,</u> makes it the most intelligent BFR cuff on the market today.</p> <p>SmartCuffs® 4.0 Features:</p> <p>Patent-pending iBFR™ LOP Calibration - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. <u>By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>

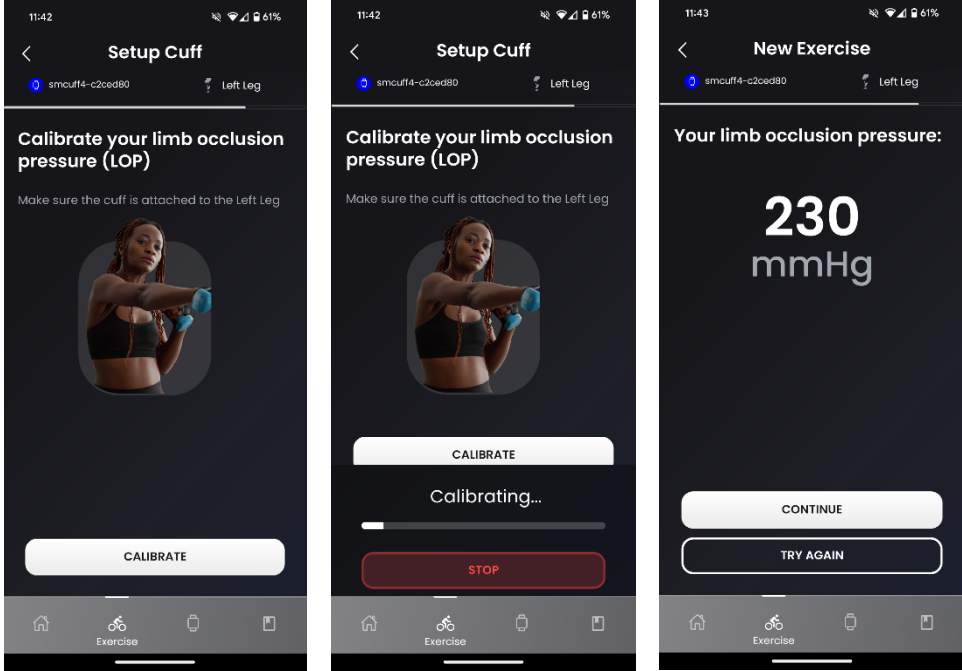
<p>Claims of the '013 Patent</p>	<p>SmartCuffs® 4.0</p>
<p>a dual-purpose tourniquet cuff having a single inflatable bladder adapted to encircle a limb;</p>	<p><i>SmartCuffs 4.0 is a dual-purpose tourniquet cuff having a single inflatable bladder that is adapted to encircle a limb.</i></p>  <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024).</p> <p>APPLYING THE SMARTCUFFS</p> <p>APPLYING THE ARM CUFF</p> <ol style="list-style-type: none"> 1 <u>Apply cuff with the buttons/LED light facing up with the housing situated on the outside of arm. Push the strap of the cuff through plastic Strap Loop. Apply as tight as possible to the upper arm.</u> The bottom flap of the cuff should slide under the top part of the cuff. 2 Connect the SmartCuffs 4.0 device to the SmartCuffs app via Bluetooth. 3 You are ready to begin to operate the SmartCuffs 4.0 device. <p><i>*To release air from the cuff in case of emergency, press down on the Emergency Air Release Button (location on page 8).</i></p> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p>

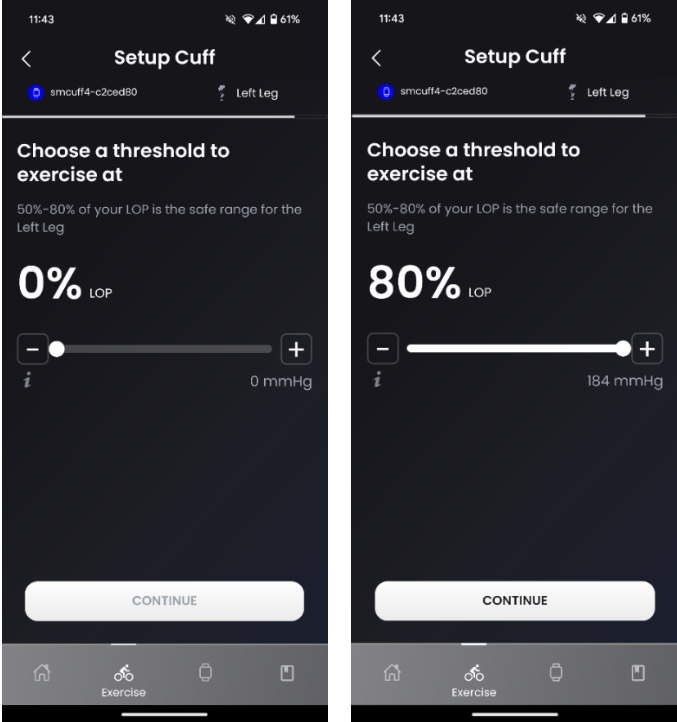
Claims of the '013 Patent	SmartCuffs® 4.0
	 <p>single inflatable bladder</p> <p>single inflatable bladder</p>

Claims of the '013 Patent	SmartCuffs® 4.0
<p>a controller selectively operating the inflatable bladder of the dual-purpose tourniquet cuff and executing instruction to control:</p>	<p><i>SmartCuffs 4.0 has a controller that selectively operates the inflatable bladder of the tourniquet cuff and executes instructions to control the sensor module, a PRP estimator, and an effector module.</i></p> <p>SPECIFICATIONS</p>  <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024).</p> 


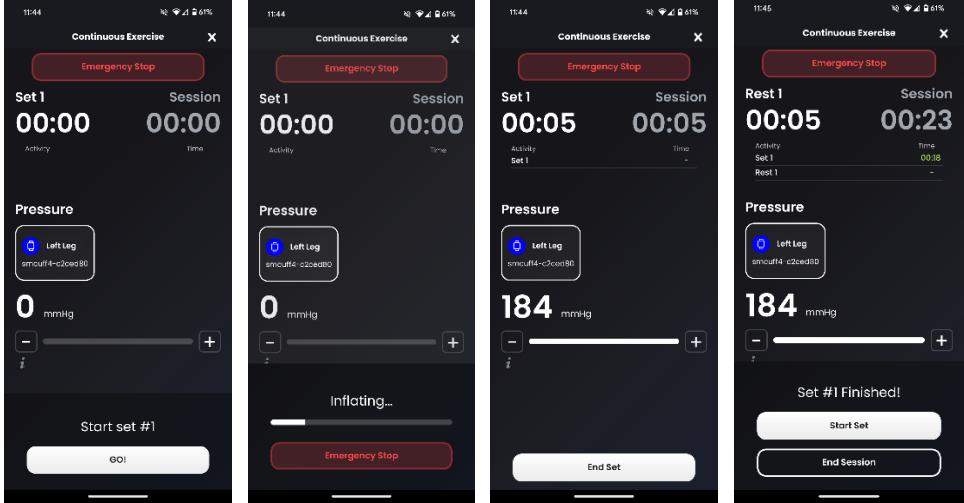
Claims of the '013 Patent	SmartCuffs® 4.0
<p>a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for measuring pressure pulsations to characterize a limb occlusion pressure (LOP), thereby to identify a minimum pressure at which arterial blood penetration past the cuff is stopped;</p>	<p><i>SmartCuffs 4.0 has a sensor module with a pulsation sensor that communicates pneumatically with the inflatable bladder for measuring pressure pulsations.</i></p> <div data-bbox="529 411 1292 926" data-label="Image"> <p>The diagram titled 'SPECIFICATIONS' shows two views of the SmartCuffs 4.0 device. The left view is a close-up of the control panel with three buttons: a red 'Emergency Air Release Button', a blue 'Bluetooth LED Indicator', and a green 'Power Button'. The right view shows the cuff with a 'Strap Loop' and a 'Pump Housing'.</p> </div> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024).</p> <div data-bbox="646 1035 1336 1787" data-label="Image"> <p>A photograph showing the internal assembly of the sensor module. A green printed circuit board (PCB) is held by a hand. A red arrow points from a box labeled 'sensor' to a small cylindrical component on the PCB. Below the PCB, a white plastic component is visible, which is part of the pneumatic communication system.</p> </div>


Claims of the '013 Patent	SmartCuffs® 4.0
	<p><i>The sensor module characterizes limb occlusion pressure (LOP) to identify a minimum pressure at which arterial blood penetration past the cuff is stopped.</i></p> <p>After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. <u>This 4.0 model, with its AI-powered processor and proprietary LOP algorithms,</u> makes it the most intelligent BFR cuff on the market today.</p> <p>SmartCuffs® 4.0 Features:</p> <p><u>Patent-pending iBFR™ LOP Calibration</u> - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. <u>By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p> <p>WHAT IS LIMB OCCLUSION PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is the amount of pressure needed to occlude arterial blood flow.</u> This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. <u>By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe</u></p> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p>


Claims of the '013 Patent	SmartCuffs® 4.0		
			
<p>a PRP estimator responsive to the sensor module for producing an estimate of a PRP, wherein the estimate of the PRP is less than the LOP and indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff; and</p>	<p><i>SmartCuffs 4.0 has a PRP estimator responsive to the sensor module for producing an estimate of a PRP, which is less than the LOP and is indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.</i></p> <p>After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. <u>This 4.0 model, with its AI-powered processor and proprietary LOP algorithms,</u> makes it the most intelligent BFR cuff on the market today.</p> <p>SmartCuffs® 4.0 Features:</p> <p>Patent-pending iBFR™ LOP Calibration - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. <u>By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>		


Claims of the '013 Patent	SmartCuffs® 4.0
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Claims of the '013 Patent	SmartCuffs® 4.0
<p>an effector module communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for maintaining pressure in the inflatable bladder near the PRP, thereby restricting but not stopping arterial blood penetration past the cuff.</p>	<p><i>SmartCuffs 4.0 has an effector module that communicates pneumatically with the inflatable bladder of the tourniquet cuff for maintaining pressure in the inflatable bladder near the PRP, thereby restricting but not stopping arterial blood penetration past the cuff.</i></p> <p>After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. <u>This 4.0 model, with its AI-powered processor and proprietary LOP algorithms,</u> makes it the most intelligent BFR cuff on the market today.</p> <p>SmartCuffs® 4.0 Features:</p> <p>Patent-pending iBFR™ LOP Calibration - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. <u>By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p> <p>WHAT IS LIMB OCCLUSION PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is the amount of pressure needed to occlude arterial blood flow.</u> This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. <u>BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe</u></p> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p>


Claims of the '013 Patent	SmartCuffs® 4.0
	 <p>The photograph shows the internal components of the SmartCuffs 4.0 device. A yellow rectangular box highlights a specific area containing a white, cylindrical component connected to a clear plastic tube. A red arrow points from a text box labeled "effector module" to this component. To the right of the highlighted area is a silver battery with the following markings: "+", "Tenergy Cell 1", "102050", "20231102", "20231102", "1000mAh".</p>
	 <p>The four screenshots illustrate the application's workflow:</p> <ul style="list-style-type: none"> Screenshot 1: Shows the "Continuous Exercise" screen with "Set 1" and "Session" both at 00:00. The pressure is 0 mmHg. A "Start set #1" button is visible at the bottom. Screenshot 2: Shows the device is "Inflating...". The pressure remains at 0 mmHg. Screenshot 3: Shows the pressure has risen to 184 mmHg. An "End Set" button is visible at the bottom. Screenshot 4: Shows the "Rest 1" phase with a timer at 00:05 and a session timer at 00:23. A "Start Set" button is visible at the bottom.

<p>Claims of the '013 Patent</p>	<p>SmartCuffs® 4.0</p>
<p>Claim 14</p>	
<p>14. An apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on a personalized restrictive pressure (PRP), comprising:</p>	<p><i>SmartCuffs 4.0 is an apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff.</i></p>  <p>See https://www.smarttoolsplus.com/smartcuffs/products/ (last accessed November 5, 2024).</p> <p>What is Blood Flow Restriction Training?</p> <p>To improve muscular strength and size it has been assumed heavy loads must be lifted. Unfortunately, in certain populations, like older individuals, post-operative patients, or those rehabilitating an injury, high-load exercises can cause injury and not be tolerated.</p> <p>Blood Flow Restriction (BFR) training is a technique in which combines low-intensity exercise under reduced arterial flow conditions. BFR is quantifiably and objectively reducing the amount of blood flow into an extremity by using a specially made medical tourniquet. BFR allows individuals to use low loads yet achieve results similar to high intensity training.</p> <p>Blood Flow Restriction (BFR) Training</p> <p>BFR training was initially developed in the 1960s in Japan and known as KAATSU training.¹</p> <p><u>Â BFR involves the application of a pneumatic cuff (tourniquet) to the upper arms or the upper legs; BFR can be applied to either one or two of the upper or lower extremities at a time but never all four limbs at one time. The cuff is then inflated to a specific pressure with the aim of obtaining partial arterial restriction and complete venous occlusion.</u> The client is then asked to perform resistance exercises at a low intensity of 20-30% of 1 repetition max (1RM), with high repetitions per set (15-30) and short rest intervals between sets (30 seconds). (2) There are non-exercising protocols for bone healing, recovery and high intensity exercise preparation.Â For example, for bicep curls one can use very light dumbbells (like 2.5 or 5lb weights) with the cuffs and still gain strength and size.Â</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>

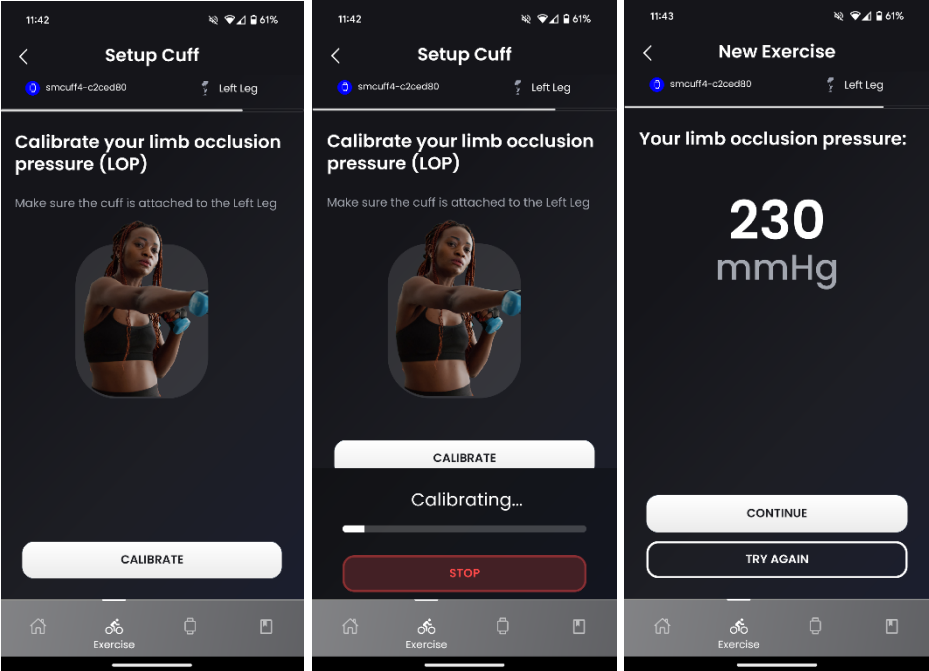
Claims of the '013 Patent	SmartCuffs® 4.0
	<p><i>SmartCuffs 4.0 provides personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on personalized restrictive pressure (PRP).</i></p> <p>After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. <u>This 4.0 model, with its AI-powered processor and proprietary LOP algorithms,</u> makes it the most intelligent BFR cuff on the market today.</p> <p>SmartCuffs® 4.0 Features:</p> <p><u>Patent-pending iBFR™ LOP Calibration - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>
<p>a dual-purpose tourniquet cuff having a single inflatable bladder adapted to encircle a limb;</p>	<p><i>SmartCuffs 4.0 is a dual-purpose tourniquet cuff having a single inflatable bladder that is adapted to encircle a limb.</i></p>  <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024).</p>

Claims of the '013 Patent	SmartCuffs® 4.0
	<p data-bbox="456 296 1008 333">APPLYING THE SMARTCUFFS</p> <p data-bbox="618 436 894 464">APPLYING THE ARM CUFF</p> <ol data-bbox="618 480 1243 716" style="list-style-type: none"><li data-bbox="618 480 1243 604">1 <u>Apply cuff with the buttons/LED light facing up with the housing situated on the outside of arm. Push the strap of the cuff through plastic Strap Loop. Apply as tight as possible to the upper arm. The bottom flap of the cuff should slide under the top part of the cuff.</u><li data-bbox="618 621 1243 669">2 Connect the SmartCuffs 4.0 device to the SmartCuffs app via Bluetooth.<li data-bbox="618 686 1243 716">3 You are ready to begin to operate the SmartCuffs 4.0 device. <p data-bbox="651 732 1227 781"><i>*To release air from the cuff in case of emergency, press down on the Emergency Air Release Button (location on page 8).</i></p> <p data-bbox="456 877 1398 947">See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p> <div data-bbox="558 963 1295 1520"><p data-bbox="431 1297 651 1381">single inflatable bladder</p></div>

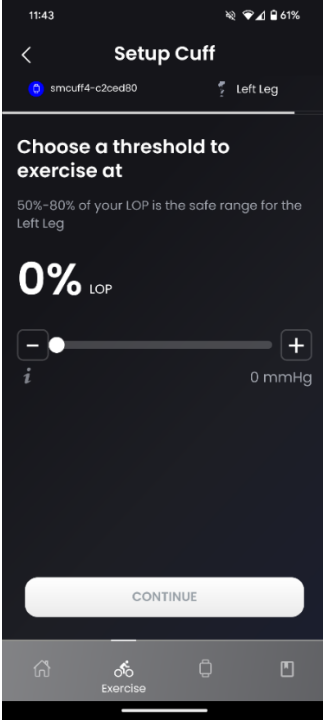
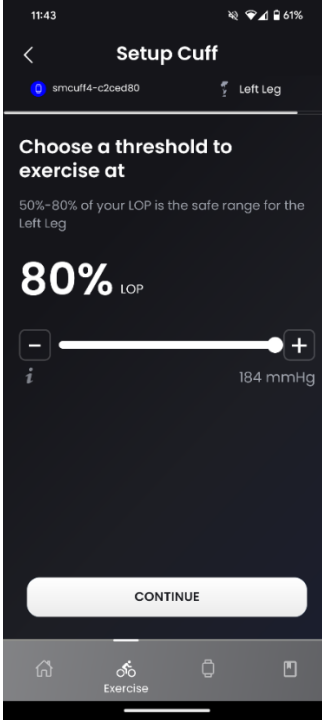
Claims of the '013 Patent	SmartCuffs® 4.0
	
<p>a controller selectively operating the inflatable bladder of the dual-purpose tourniquet cuff, the controller executing instructions to control:</p>	<p><i>SmartCuffs 4.0 has a controller that selectively operates the inflatable bladder of the tourniquet cuff and executes instructions to control the sensor module, a PRP estimator, and an effector module.</i></p> <div data-bbox="529 993 1292 1509"> <p>SPECIFICATIONS</p>  </div> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024).</p>

Claims of the '013 Patent	SmartCuffs® 4.0
	
<p>a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for measuring pressure pulsations to characterize a limb occlusion pressure (LOP), thereby to identify a minimum pressure at which arterial blood penetration past the cuff is stopped; and</p>	<p><i>SmartCuffs 4.0 has a sensor module with a pulsation sensor that communicates pneumatically with the inflatable bladder for measuring pressure pulsations.</i></p> <div data-bbox="529 800 1292 1314" data-label="Image"> </div> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024).</p>

Claims of the '013 Patent	SmartCuffs® 4.0
	<div data-bbox="646 285 1211 1035" data-label="Image"> </div> <p data-bbox="435 1052 1393 1161"><i>The sensor module characterizes limb occlusion pressure (LOP) to identify a minimum pressure at which arterial blood penetration past the cuff is stopped.</i></p> <p data-bbox="462 1190 1357 1325">After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. <u>This 4.0 model, with its AI-powered processor and proprietary LOP algorithms,</u> makes it the most intelligent BFR cuff on the market today.</p> <p data-bbox="462 1398 815 1430">SmartCuffs® 4.0 Features:</p> <p data-bbox="462 1478 1357 1577"><u>Patent-pending iBFR™ LOP Calibration</u> - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. <u>By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></p> <p data-bbox="469 1617 1382 1686">See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>


Claims of the '013 Patent	SmartCuffs® 4.0
	<p>WHAT IS LIMB OCCLUSION PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is the amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe</u></p> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p> 




Claims of the '013 Patent	SmartCuffs® 4.0
<p>a PRP estimator responsive to the sensor module for producing an estimate of a PRP, wherein the estimate of the PRP is less than the LOP and indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.</p>	<p><i>SmartCuffs 4.0 has a PRP estimator responsive to the sensor module for producing an estimate of a PRP, which is less than the LOP and is indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.</i></p> <p>After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. <u>This 4.0 model, with its AI-powered processor and proprietary LOP algorithms,</u> makes it the most intelligent BFR cuff on the market today.</p> <p>SmartCuffs® 4.0 Features:</p> <p>Patent-pending iBFR™ LOP Calibration - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. <u>By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p> <p>WHAT IS LIMB OCCLUSION PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is the amount of pressure needed to occlude arterial blood flow.</u> This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. <u>BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe</u></p> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p>




Claims of the '013 Patent	SmartCuffs® 4.0	
	 <p>The screenshot shows the 'Setup Cuff' screen for the left leg. It prompts the user to 'Choose a threshold to exercise at' and provides a range of 50%-80% of LOP. The selected threshold is 0% LOP, which corresponds to 0 mmHg. A slider control is shown with the marker at the 0% position. A 'CONTINUE' button is at the bottom.</p>	 <p>The screenshot shows the 'Setup Cuff' screen for the left leg. It prompts the user to 'Choose a threshold to exercise at' and provides a range of 50%-80% of LOP. The selected threshold is 80% LOP, which corresponds to 184 mmHg. A slider control is shown with the marker at the 80% position. A 'CONTINUE' button is at the bottom.</p>


30. On information and belief, Defendant has made, used, imported, sold, and/or offered to sell the SmartCuffs® 3.0 Pro. The claim chart below shows how at least independent claims 1 and 14 of the '013 patent read on the SmartCuffs® 3.0 Pro, based on information currently available to Plaintiff and their attorneys. This claim chart is not intended to limit the scope of Plaintiff's infringement claim in any way and is intended to be without prejudice to Plaintiff's ability to assert different or additional claims of the '013 patent against Defendant and/or to apply such claims to the SmartCuffs® 3.0 Pro differently in view of additional information that Plaintiff and their attorneys may acquire during the course of this litigation.

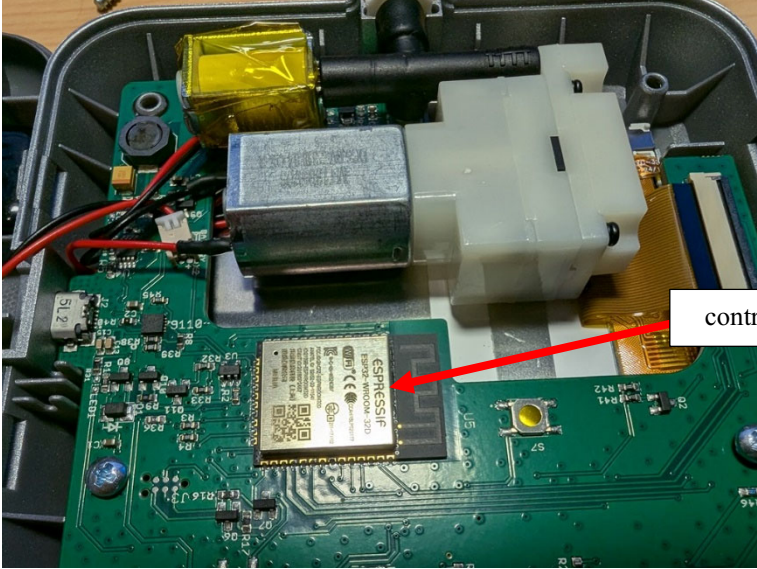


31. The SmartCuffs® 3.0 Pro meets each element of claims 1 and 14 of the '013 patent:

<p>Claims of the '013 Patent</p>	<p>SmartCuffs® 3.0 Pro</p>
<p>Claim 1</p>	
<p>1. Apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on a personalized restrictive pressure (PRP), comprising:</p>	<p><i>SmartCuffs 3.0 Pro is an apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff.</i></p>  <p>See https://www.smarttoolsplus.com/smartcuffs/products/ (last accessed November 5, 2024).</p> <p>What is Blood Flow Restriction Training?</p> <p>To improve muscular strength and size it has been assumed heavy loads must be lifted. Unfortunately, in certain populations, like older individuals, post-operative patients, or those rehabilitating an injury, high-load exercises can cause injury and not be tolerated.</p> <p>Blood Flow Restriction (BFR) training is a technique in which combines low-intensity exercise under reduced arterial flow conditions. BFR is quantifiably and objectively reducing the amount of blood flow into an extremity by using a specially made medical tourniquet. BFR allows individuals to use low loads yet achieve results similar to high intensity training.</p> <p>Blood Flow Restriction (BFR) Training</p> <p>BFR training was initially developed in the 1960s in Japan and known as KAATSU training.¹</p> <p>Â BFR involves the application of a pneumatic cuff (tourniquet) to the upper arms or the upper legs. BFR can be applied to either one or two of the upper or lower extremities at a time but never all four limbs at one time. The cuff is then inflated to a specific pressure with the aim of obtaining partial arterial restriction and complete venous occlusion. The client is then asked to perform resistance exercises at a low intensity of 20-30% of 1 repetition max (1RM), with high repetitions per set (15-30) and short rest intervals between sets (30 seconds). (2) There are non-exercising protocols for bone healing, recovery and high intensity exercise preparation.Â For example, for bicep curls one can use very light dumbbells (like 2.5 or 5lb weights) with the cuffs and still gain strength and size.Â</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>

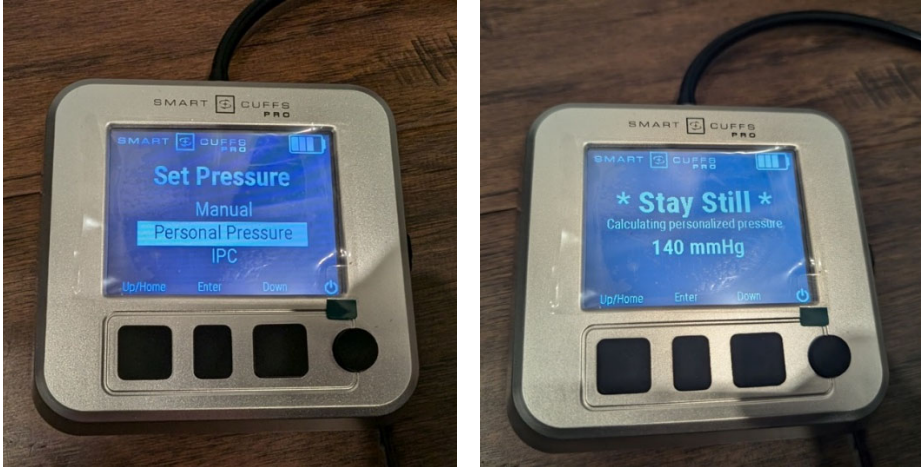
Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	<p><i>SmartCuffs 3.0 Pro provides personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on personalized restrictive pressure (PRP).</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body. There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p>
<p>a dual-purpose tourniquet cuff having a single inflatable bladder adapted to encircle a limb;</p>	<p><i>SmartCuffs 3.0 Pro is a dual-purpose tourniquet cuff having a single inflatable bladder that is adapted to encircle a limb.</i></p>  <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024).</p>

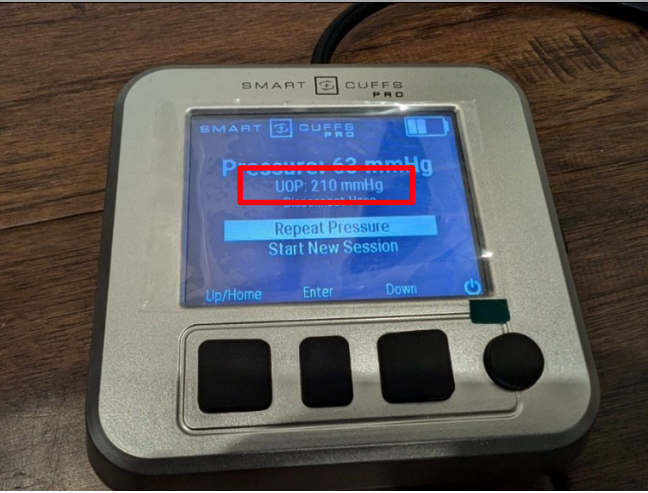


Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	<p data-bbox="451 300 976 333">APPLYING THE SMARTCUFFS</p> <p data-bbox="451 388 716 409">APPLYING THE ARM CUFF</p> <div data-bbox="451 432 899 835">  </div> <ol data-bbox="930 432 1380 758" style="list-style-type: none"> 1 Apply cuff with the logo readable with valve on the outside of arm. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper arm. The bottom flap of the cuff should slide under the top part of the cuff. 2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard. 3 You are ready to begin to operate the SmartCuffs PRO device. <p data-bbox="959 787 1380 898"><i>*To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.</i></p> <div data-bbox="634 972 1380 1018" style="border: 1px solid black; padding: 5px; text-align: center;">  <p>For more detailed information, videos, and instruction, download our SmartCuffs® Academy app on the Apple App Store or Google Play Store.</p> </div> <p data-bbox="461 1060 716 1081">APPLYING THE LEG CUFF</p> <div data-bbox="467 1104 909 1512">  </div> <ol data-bbox="940 1104 1390 1430" style="list-style-type: none"> 1 Apply cuff with the logo readable with valve on the outside of leg. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper leg. The bottom flap of the cuff should slide under the top part of the cuff. 2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard. 3 You are ready to begin to operate the SmartCuffs PRO device. <p data-bbox="969 1459 1390 1570"><i>*To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.</i></p> <p data-bbox="454 1640 1390 1707">See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024).</p>


Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	
<p>a controller selectively operating the inflatable bladder of the dual-purpose tourniquet cuff and executing instruction to control:</p>	<p><i>SmartCuffs 3.0 Pro has a controller that selectively operates the inflatable bladder of the tourniquet cuff and executes instructions to control the sensor module, a PRP estimator, and an effector module.</i></p>



Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	
<p>a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for measuring pressure pulsations to characterize a limb occlusion pressure (LOP), thereby to identify a minimum pressure at which arterial blood penetration past the cuff is stopped;</p>	<p><i>SmartCuffs 3.0 Pro has a sensor module with a pulsation sensor that communicates pneumatically with the inflatable bladder for measuring pressure pulsations.</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the <u>built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p>

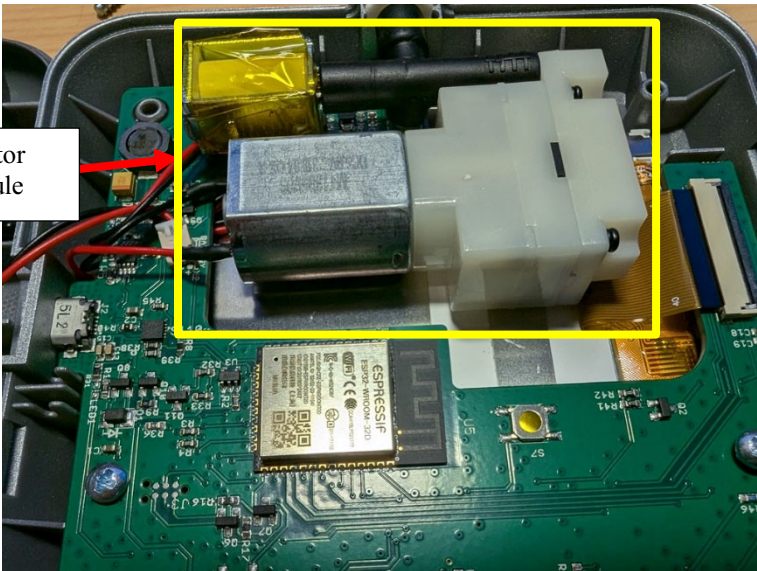
Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	<div data-bbox="548 285 1300 850" data-label="Image"> </div> <p data-bbox="430 867 1414 974"><i>The sensor module characterizes limb occlusion pressure (LOP) to identify a minimum pressure at which arterial blood penetration past the cuff is stopped.</i></p> <p data-bbox="440 995 654 1018">BFR CUFF PRESSURE</p> <p data-bbox="440 1031 930 1052">There are different methods to determine proper BFR cuff pressures.</p> <p data-bbox="440 1077 1398 1161">A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.</u></p> <p data-bbox="440 1184 1393 1245">Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p data-bbox="440 1268 1273 1289">The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p data-bbox="440 1314 1390 1375">The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p data-bbox="467 1415 1380 1486">See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>

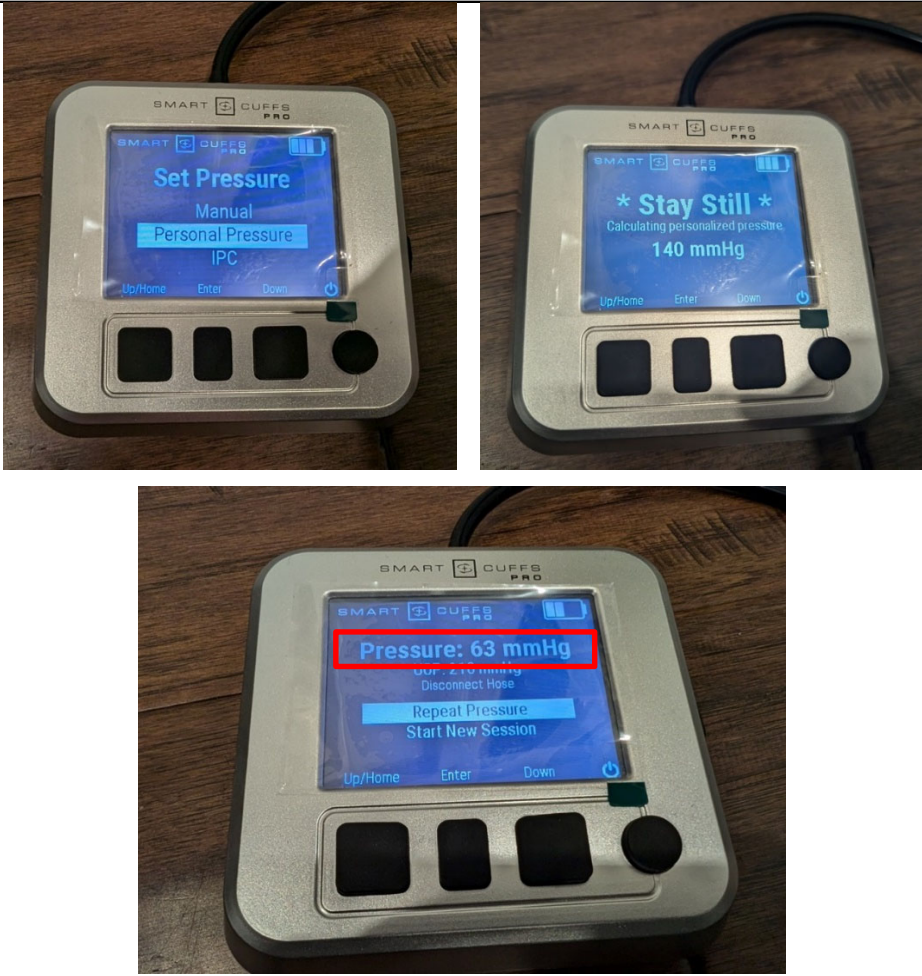
Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	<p>WHAT IS LIMB OCCLUSION PRESSURE (LOP)?</p> <p><u>Limb Occlusion Pressure (LOP) is the minimal amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? LOP/"Personalized Pressure" should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>RECOMMENDED % OF LOP:</p> <p>FOR THE ARM* 30%-50% LOP FOR THE LEG* 50%-80% LOP</p> <p><i>*Operating LOP tolerance +/- 15mmHg</i></p> <p>See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024) (annotated).</p> 


Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	
<p>a PRP estimator responsive to the sensor module for producing an estimate of a PRP, wherein the estimate of the PRP is less than the LOP and indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff; and</p>	<p><i>SmartCuffs 3.0 Pro has a PRP estimator responsive to the sensor module for producing an estimate of a PRP, which is less than the LOP and is indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the <u>built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p>A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff.A. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculatedA by the SmartCuffs BFR cuffA as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are Å exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>




Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	<p data-bbox="483 296 1279 333">WHAT IS LIMB OCCLUSION PRESSURE (LOP)?</p> <p data-bbox="483 382 1370 514"><u>Limb Occlusion Pressure (LOP) is the minimal amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></p> <p data-bbox="483 560 889 581">HOW OFTEN SHOULD IT BE MEASURED?</p> <p data-bbox="483 583 1360 625">LOP/"Personalized Pressure" should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p data-bbox="483 674 760 695">RECOMMENDED % OF LOP:</p> <p data-bbox="483 705 764 726">FOR THE ARM* 30%-50% LOP</p> <p data-bbox="483 737 764 758">FOR THE LEG* 50%-80% LOP</p> <p data-bbox="483 919 768 940">*Operating LOP tolerance +/- 15mmHg</p> <p data-bbox="464 974 1386 1079">See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024) (annotated).</p>  A photograph of the SmartCuffs Pro device. The device is a rectangular, light-colored unit with a screen and several buttons. The screen displays the text "Choose UOP%" and "30%". Below the screen are four buttons labeled "Up/Home", "Enter", "Down", and a power button. The device is resting on a wooden surface.


Claims of the '013 Patent	SmartCuffs® 3.0 Pro
<p>an effector module communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for maintaining pressure in the inflatable bladder near the PRP, thereby restricting but not stopping arterial blood penetration past the cuff.</p>	<p><i>SmartCuffs 3.0 Pro has an effector module that communicates pneumatically with the inflatable bladder of the tourniquet cuff for maintaining pressure in the inflatable bladder near the PRP, thereby restricting but not stopping arterial blood penetration past the cuff.</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the <u>built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p>A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>


Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	<p style="text-align: center;">WHAT IS LIMB OCCLUSION PRESSURE (LOP)?</p> <p><u>Limb Occlusion Pressure (LOP) is the minimal amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? LOP/"Personalized Pressure" should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>RECOMMENDED % OF LOP:</p> <p>FOR THE ARM* 30%-50% LOP FOR THE LEG* 50%-80% LOP</p> <p style="text-align: center;"><i>*Operating LOP tolerance +/- 15mmHg</i></p> <p style="text-align: center;">See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024) (annotated).</p> <div style="text-align: center;">  </div>

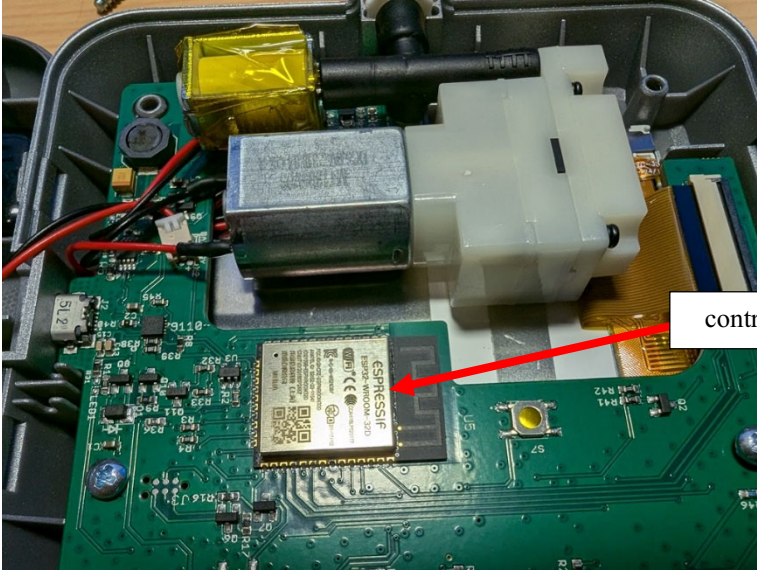


Claims of the '013 Patent	SmartCuffs® 3.0 Pro	
	 <p>The image displays three sequential screenshots of the SmartCuffs 3.0 Pro device's LCD screen. The device is a handheld unit with a screen and four buttons below it. The top-left screenshot shows the 'Set Pressure' menu with options for 'Manual', 'Personal Pressure', and 'IPC'. The top-right screenshot shows a 'Stay Still' instruction with a 'Calculating personalized pressure' status and a '140 mmHg' target. The bottom-center screenshot shows the final 'Pressure: 63 mmHg' reading, with the text highlighted by a red box. Below the reading are options to 'Repeat Pressure' or 'Start New Session'.</p>	

<p>Claims of the '013 Patent</p>	<p>SmartCuffs® 3.0 Pro</p>
<p>Claim 14</p>	
<p>14. An apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on a personalized restrictive pressure (PRP), comprising:</p>	<p><i>SmartCuffs 3.0 Pro is an apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff.</i></p>  <p>See https://www.smarttoolsplus.com/smartcuffs/products/ (last accessed November 5, 2024).</p> <p>What is Blood Flow Restriction Training?</p> <p>To improve muscular strength and size it has been assumed heavy loads must be lifted. Unfortunately, in certain populations, like older individuals, post-operative patients, or those rehabilitating an injury, high-load exercises can cause injury and not be tolerated.</p> <p>Blood Flow Restriction (BFR) training is a technique in which combines low-intensity exercise under reduced arterial flow conditions. BFR is quantifiably and objectively reducing the amount of blood flow into an extremity by using a specially made medical tourniquet. BFR allows individuals to use low loads yet achieve results similar to high intensity training.</p> <p>Blood Flow Restriction (BFR) Training</p> <p>BFR training was initially developed in the 1960s in Japan and known as KAATSU training.¹</p> <p>Â BFR involves the application of a pneumatic cuff (tourniquet) to the upper arms or the upper legs. BFR can be applied to either one or two of the upper or lower extremities at a time but never all four limbs at one time. The cuff is then inflated to a specific pressure with the aim of obtaining partial arterial restriction and complete venous occlusion. The client is then asked to perform resistance exercises at a low intensity of 20-30% of 1 repetition max (1RM), with high repetitions per set (15-30) and short rest intervals between sets (30 seconds). (2) There are non-exercising protocols for bone healing, recovery and high intensity exercise preparation.Â For example, for bicep curls one can use very light dumbbells (like 2.5 or 5lb weights) with the cuffs and still gain strength and size.Â</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>

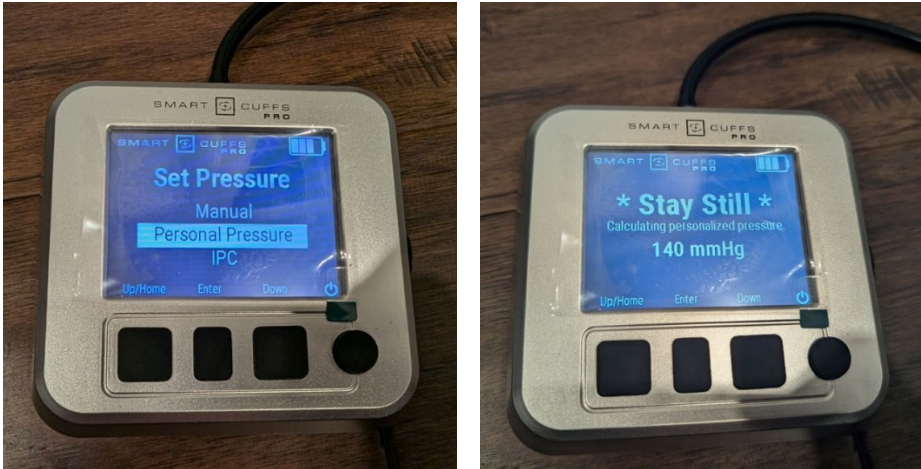
Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	<p><i>SmartCuffs 3.0 Pro provides personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on personalized restrictive pressure (PRP).</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: <u>The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body. There is no need for an external doppler probe or hand pump. The unit will do everything for you.</u></p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p>
<p>a dual-purpose tourniquet cuff having a single inflatable bladder adapted to encircle a limb;</p>	<p><i>SmartCuffs 3.0 Pro is a dual-purpose tourniquet cuff having a single inflatable bladder that is adapted to encircle a limb.</i></p>  <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024).</p>

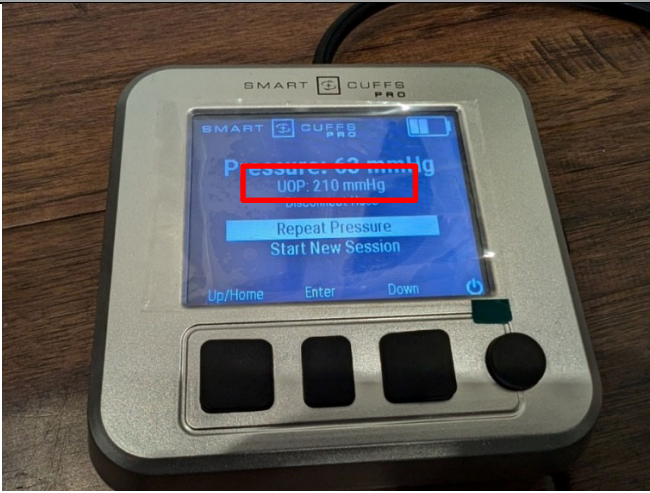


Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	<p data-bbox="451 300 976 336">APPLYING THE SMARTCUFFS</p> <p data-bbox="451 388 719 411">APPLYING THE ARM CUFF</p> <div data-bbox="451 432 899 840">  </div> <ol data-bbox="930 432 1380 762" style="list-style-type: none"> 1 Apply cuff with the logo readable with valve on the outside of arm. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper arm. The bottom flap of the cuff should slide under the top part of the cuff. 2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard. 3 You are ready to begin to operate the SmartCuffs PRO device. <p data-bbox="959 787 1380 903"><i>*To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.</i></p> <div data-bbox="634 972 1380 1020" style="border: 1px solid black; padding: 5px; text-align: center;">  <p>For more detailed information, videos, and instruction, download our SmartCuffs® Academy app on the Apple App Store or Google Play Store.</p> </div> <p data-bbox="461 1060 719 1083">APPLYING THE LEG CUFF</p> <div data-bbox="467 1104 909 1512">  </div> <ol data-bbox="940 1104 1390 1434" style="list-style-type: none"> 1 Apply cuff with the logo readable with valve on the outside of leg. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper leg. The bottom flap of the cuff should slide under the top part of the cuff. 2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard. 3 You are ready to begin to operate the SmartCuffs PRO device. <p data-bbox="969 1459 1390 1575"><i>*To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.</i></p> <p data-bbox="454 1638 1390 1707">See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024).</p>


Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	 <p>The image contains two photographs of the SmartCuffs 3.0 Pro device. The top photograph shows the black fabric cuff and the silver electronic device on a wooden surface. A red arrow points from a callout box labeled "single inflatable bladder" to the cuff. The device's screen displays "Pressure: 120 mmHg" and "MAP: 92". The bottom photograph is a close-up of the cuff's bladder, with a red arrow pointing from a callout box labeled "single inflatable bladder" to it.</p>

Claims of the '013 Patent	SmartCuffs® 3.0 Pro
<p>a controller selectively operating the inflatable bladder of the dual-purpose tourniquet cuff, the controller executing instructions to control:</p>	<p><i>SmartCuffs 3.0 Pro has a controller that selectively operates the inflatable bladder of the tourniquet cuff and executes instructions to control the sensor module, a PRP estimator, and an effector module.</i></p> 
<p>a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for measuring pressure pulsations to characterize a limb occlusion pressure (LOP), thereby to identify a minimum pressure at which arterial blood penetration</p>	<p><i>SmartCuffs 3.0 Pro has a sensor module with a pulsation sensor that communicates pneumatically with the inflatable bladder for measuring pressure pulsations.</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the <u>built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p>

Claims of the '013 Patent	SmartCuffs® 3.0 Pro
<p>past the cuff is stopped; and</p>	<div data-bbox="548 285 1300 850" data-label="Image"> </div> <p data-bbox="1175 684 1365 745">sensor</p> <p data-bbox="430 867 1414 974"><i>The sensor module characterizes limb occlusion pressure (LOP) to identify a minimum pressure at which arterial blood penetration past the cuff is stopped.</i></p> <p data-bbox="440 995 654 1018">BFR CUFF PRESSURE</p> <p data-bbox="440 1031 930 1052">There are different methods to determine proper BFR cuff pressures.</p> <p data-bbox="440 1077 1398 1159">A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.</u></p> <p data-bbox="440 1184 1393 1245">Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p data-bbox="440 1270 1276 1291">The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p data-bbox="440 1316 1390 1377">The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p data-bbox="467 1415 1382 1486">See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>

Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	<p data-bbox="483 296 1279 336">WHAT IS LIMB OCCLUSION PRESSURE (LOP)?</p> <p data-bbox="483 382 1370 516"><u>Limb Occlusion Pressure (LOP) is the minimal amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></p> <p data-bbox="483 560 889 583">HOW OFTEN SHOULD IT BE MEASURED?</p> <p data-bbox="483 583 1360 630">LOP/"Personalized Pressure" should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p data-bbox="483 674 760 697">RECOMMENDED % OF LOP:</p> <p data-bbox="483 705 764 728">FOR THE ARM* 30%-50% LOP</p> <p data-bbox="483 737 764 760">FOR THE LEG* 50%-80% LOP</p> <p data-bbox="483 919 768 942">*Operating LOP tolerance +/- 15mmHg</p> <p data-bbox="464 974 1386 1081">See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024) (annotated).</p> <div data-bbox="467 1096 1382 1562"></div>


Claims of the '013 Patent	SmartCuffs® 3.0 Pro
	
<p>a PRP estimator responsive to the sensor module for producing an estimate of a PRP, wherein the estimate of the PRP is less than the LOP and indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.</p>	<p><i>SmartCuffs 3.0 Pro has a PRP estimator responsive to the sensor module for producing an estimate of a PRP, which is less than the LOP and is indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the <u>built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p>A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff.A. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculatedA by the SmartCuffs BFR cuffA as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are Å exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>


<p>Claims of the '013 Patent</p>	<p align="center">SmartCuffs® 3.0 Pro</p>
	<p align="center">WHAT IS LIMB OCCLUSION PRESSURE (LOP)?</p> <p><u>Limb Occlusion Pressure (LOP) is the minimal amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? LOP/"Personalized Pressure" should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>RECOMMENDED % OF LOP: FOR THE ARM* 30%-50% LOP FOR THE LEG* 50%-80% LOP</p> <p><i>*Operating LOP tolerance +/- 15mmHg</i></p> <p>See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024) (annotated).</p> 

32. On information and belief, Defendant has made, used, imported, sold, and/or offered to sell the SmartCuffs® 3.0. The claim chart below shows how at least independent claims 1 and 14 of the '013 patent read on the SmartCuffs® 3.0, based on information currently




available to Plaintiff and their attorneys. This claim chart is not intended to limit the scope of Plaintiff’s infringement claim in any way and is intended to be without prejudice to Plaintiff’s ability to assert different or additional claims of the ’013 patent against Defendant and/or to apply such claims to the SmartCuffs® 3.0 differently in view of additional information that Plaintiff and their attorneys may acquire during the course of this litigation.



33. The SmartCuffs® 3.0 meets each element of claims 1 and 14 of the ’013 patent:


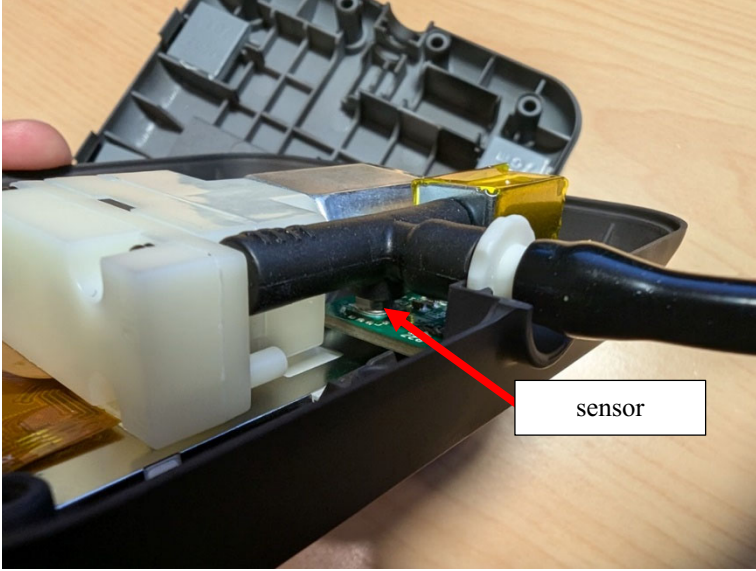
Claims of the ‘013 Patent	SmartCuffs® 3.0
Claim 1	
<p>1. Apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on a personalized restrictive pressure (PRP), comprising:</p>	<p><i>SmartCuffs 3.0 is an apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff.</i></p>  <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024).</p>

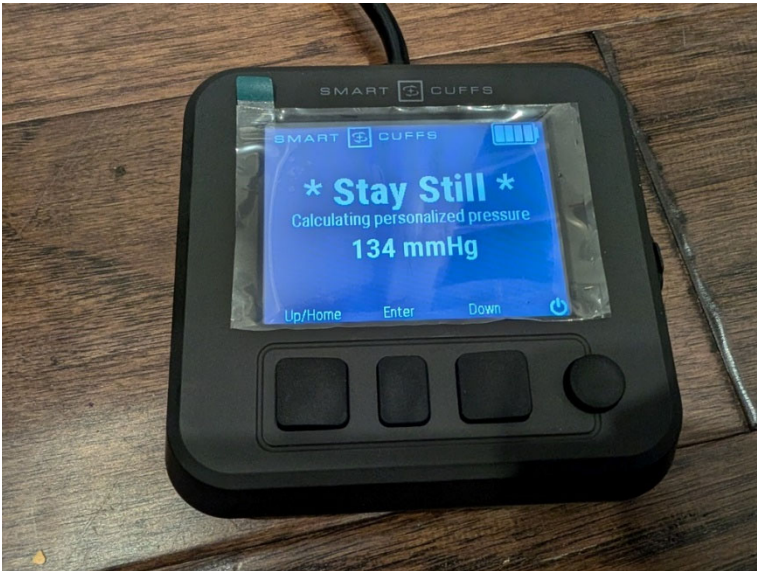
Claims of the '013 Patent	SmartCuffs® 3.0
	<p>What is Blood Flow Restriction Training?</p> <p>To improve muscular strength and size it has been assumed heavy loads must be lifted. Unfortunately, in certain populations, like older individuals, post-operative patients, or those rehabilitating an injury, high-load exercises can cause injury and not be tolerated.</p> <p>Blood Flow Restriction (BFR) training is a technique in which combines low-intensity exercise under reduced arterial flow conditions. BFR is quantifiably and objectively reducing the amount of blood flow into an extremity by using a specially made medical tourniquet. BFR allows individuals to use low loads yet achieve results similar to high intensity training.</p> <p>Blood Flow Restriction (BFR) Training</p> <p>BFR training was initially developed in the 1960s in Japan and known as KAATSU training.¹</p> <p>Â BFR involves the application of a pneumatic cuff (tourniquet) to the upper arms or the upper legs. BFR can be applied to either one or two of the upper or lower extremities at a time but never all four limbs at one time. <u>The cuff is then inflated to a specific pressure with the aim of obtaining partial arterial restriction and complete venous occlusion.</u> The client is then asked to perform resistance exercises at a low intensity of 20-30% of 1 repetition max (1RM), with high repetitions per set (15-30) and short rest intervals between sets (30 seconds). (2) There are non-exercising protocols for bone healing, recovery and high intensity exercise preparation.Â For example, for bicep curls one can use very light dumbbells (like 2.5 or 5lb weights) with the cuffs and still gain strength and size.Â</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p> <p><i>SmartCuffs 3.0 provides personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on personalized restrictive pressure (PRP).</i></p> <p> Personalized Pressure feature: This feature allows for a fast, hassle-free personalized pressure calculation. <u>With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. This unit will do everything for you.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>


Claims of the '013 Patent	SmartCuffs® 3.0
<p>a dual-purpose tourniquet cuff having a single inflatable bladder adapted to encircle a limb;</p>	<p><i>SmartCuffs 3.0 is a dual-purpose tourniquet cuff having a single inflatable bladder that is adapted to encircle a limb.</i></p>  <p>The image shows two black, cylindrical inflatable cuffs stacked vertically on the left. To their right is a grey rectangular control unit with a screen and buttons, and a black stethoscope. The cuffs have a silver valve on the front. The control unit has 'SMART CUFFS' printed on it.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024).</p> <p>APPLYING THE SMARTCUFFS</p> <p>APPLYING THE ARM CUFF</p>  <p>The image shows a man in a grey t-shirt having a black SmartCuff applied to his upper arm by another man in a black t-shirt. The man in black is holding the cuff and adjusting it around the arm.</p> <ol style="list-style-type: none"> 1 Apply cuff with the logo readable with valve on the outside of arm. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper arm. The bottom flap of the cuff should slide under the top part of the cuff. 2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard. 3 You are ready to begin to operate the SmartCuffs device. <p><i>*To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.</i></p>


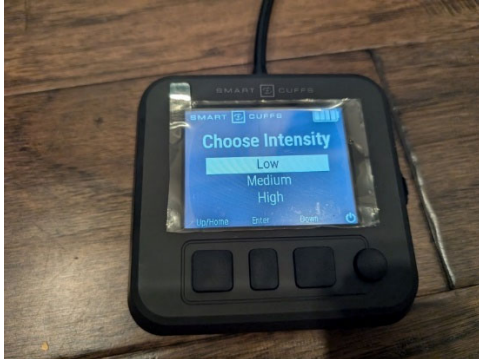

Claims of the '013 Patent	SmartCuffs® 3.0
	<p data-bbox="634 317 1382 365"> For more detailed information, videos, and instruction, download our SmartCuffs® Academy app on the Apple App Store or Google Play Store.</p> <p data-bbox="461 407 716 428">APPLYING THE LEG CUFF</p> <div data-bbox="467 453 907 858"></div> <ol data-bbox="943 449 1390 779" style="list-style-type: none">1 Apply cuff with the logo readable with valve on the outside of leg. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper leg. The bottom flap of the cuff should slide under the top part of the cuff.2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard.3 You are ready to begin to operate the SmartCuffs device. <p data-bbox="971 810 1390 926"><i>*To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.</i></p> <p data-bbox="505 961 1344 1031">See https://www.smarttoolsplus.com/images/store/bfr%20user%20manual%202021%20low21.pdf (last accessed November 5, 2024).</p> <div data-bbox="467 1050 1300 1612"><p data-bbox="467 1140 686 1220">single inflatable bladder</p></div>

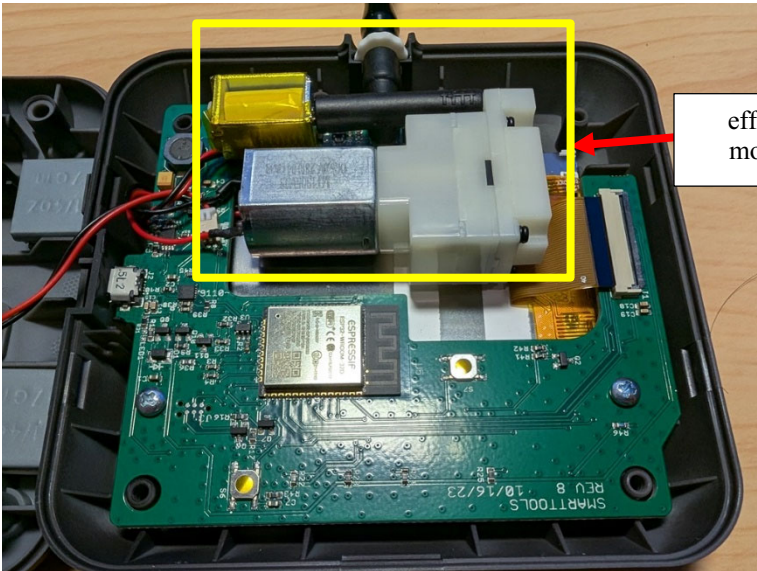
Claims of the '013 Patent	SmartCuffs® 3.0
	 <p>A photograph of the SmartCuffs 3.0 device, which is a grey, rectangular, handheld unit with several buttons on top. A black fabric cuff is attached to the side. A red arrow points from a callout box labeled "single inflatable bladder" to the cuff.</p>
<p>a controller selectively operating the inflatable bladder of the dual-purpose tourniquet cuff and executing instruction to control:</p>	<p><i>SmartCuffs 3.0 has a controller that selectively operates the inflatable bladder of the tourniquet cuff and executes instructions to control the sensor module, a PRP estimator, and an effector module.</i></p>  <p>A photograph showing the internal components of the SmartCuffs 3.0 device. A green printed circuit board (PCB) is visible, featuring a central microcontroller chip, a yellow battery, and various electronic components. A red arrow points from a callout box labeled "controller" to the microcontroller chip. The PCB is labeled "SMARTTOOLS" and "REV 8 10/16/23".</p>

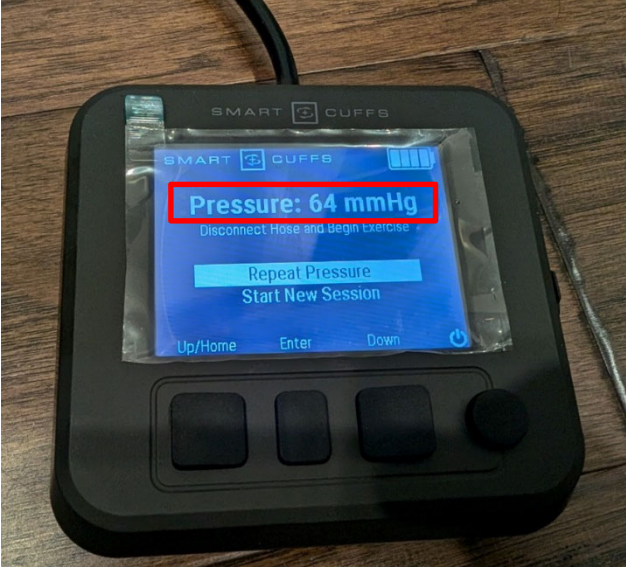

Claims of the '013 Patent	SmartCuffs® 3.0
<p>a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for measuring pressure pulsations to characterize a limb occlusion pressure (LOP), thereby to identify a minimum pressure at which arterial blood penetration past the cuff is stopped;</p>	<p><i>SmartCuffs 3.0 has a sensor module with a pulsation sensor that communicates pneumatically with the inflatable bladder for measuring pressure pulsations.</i></p> <p> Personalized Pressure feature: This feature allows for a fast, hassle-free personalized pressure calculation. <u>With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. This unit will do everything for you.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>  <p><i>The sensor module characterizes limb occlusion pressure (LOP) to identify a minimum pressure at which arterial blood penetration past the cuff is stopped.</i></p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p>A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>


<p>Claims of the '013 Patent</p>	<p align="center">SmartCuffs® 3.0</p>
	<p>WHAT IS LIMB OCCLUSION PRESSURE & UPPER OPERATIONAL PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is then calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%–80%. Personalized Pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. <u>By establishing a baseline UOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? Personalized Pressure should be measured every 2–4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>WITH THIS SMARTCUFFS DEVICE, WE USE THE FOLLOWING INTENSITY LEVELS TO CORRESPOND TO UOP%:</p> <p>FOR THE ARM* Low = 30% UOP, Medium = 40% UOP, and High = 50% UOP FOR THE LEG* Low = 50% UOP, Medium = 65% UOP, and High = 80% UOP</p> <p><small>*Operating UOP tolerance +/-15mmHg</small></p> <p>See https://www.smarttoolsplus.com/images/store/bfr%20user%20manual%202021%20low21.pdf (last accessed November 5, 2024) (annotated).</p> 

Claims of the '013 Patent	SmartCuffs® 3.0
<p>a PRP estimator responsive to the sensor module for producing an estimate of a PRP, wherein the estimate of the PRP is less than the LOP and indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff; and</p>	<p><i>SmartCuffs 3.0 has a PRP estimator responsive to the sensor module for producing an estimate of a PRP, which is less than the LOP and is indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.</i></p> <p> Personalized Pressure feature: This feature allows for a fast, hassle-free personalized pressure calculation. With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body. There is no need for an external doppler probe or hand pump. This unit will do everything for you.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p>A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p> <div style="border: 1px solid black; padding: 10px; margin-top: 10px;"> <p>WHAT IS LIMB OCCLUSION PRESSURE & UPPER OPERATIONAL PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is then calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%. Personalized Pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. By establishing a baseline UOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? Personalized Pressure should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>WITH THIS SMARTCUFFS DEVICE, WE USE THE FOLLOWING INTENSITY LEVELS TO CORRESPOND TO UOP%:</p> <p>FOR THE ARM* Low = 30% UOP, Medium = 40% UOP, and High = 50% UOP FOR THE LEG* Low = 50% UOP, Medium = 65% UOP, and High = 80% UOP</p> <p><small>*Operating UOP tolerance +/-15mmHg</small></p> </div>

<p>Claims of the '013 Patent</p>	<p>SmartCuffs® 3.0</p>
	<p>See https://www.smarttoolsplus.com/images/store/bfr%20user%20manual%202021%20low21.pdf (last accessed November 5, 2024) (annotated).</p> <div style="display: flex; justify-content: space-around;">   </div>
<p>an effector module communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for maintaining pressure in the inflatable bladder near the PRP, thereby restricting but not stopping arterial blood penetration past the cuff.</p>	<p><i>SmartCuffs 3.0 has an effector module that communicates pneumatically with the inflatable bladder of the tourniquet cuff for maintaining pressure in the inflatable bladder near the PRP, thereby restricting but not stopping arterial blood penetration past the cuff.</i></p> <p> Personalized Pressure feature: This feature allows for a fast, hassle-free personalized pressure calculation. With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body. There is no need for an external doppler probe or hand pump. This unit will do everything for you.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p>A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>



<p>Claims of the '013 Patent</p>	<p align="center">SmartCuffs® 3.0</p>
	<p>WHAT IS LIMB OCCLUSION PRESSURE & UPPER OPERATIONAL PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is then calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%–80%. Personalized Pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. <u>By establishing a baseline UOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? Personalized Pressure should be measured every 2–4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>WITH THIS SMARTCUFFS DEVICE, WE USE THE FOLLOWING INTENSITY LEVELS TO CORRESPOND TO UOP%:</p> <p>FOR THE ARM* Low = 30% UOP, Medium = 40% UOP, and High = 50% UOP FOR THE LEG* Low = 50% UOP, Medium = 65% UOP, and High = 80% UOP</p> <p><small>*Operating UOP tolerance +/-15mmHg</small></p> <p>See https://www.smarttoolsplus.com/images/store/bfr%20user%20manual%202021%20low21.pdf (last accessed November 5, 2024) (annotated).</p> 


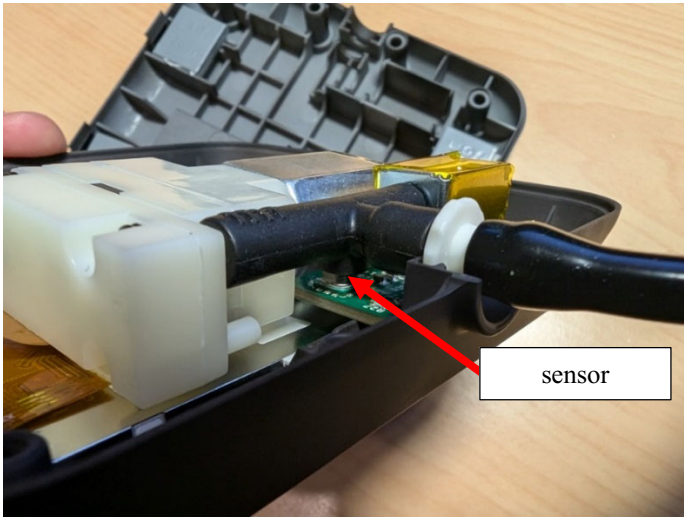
<p>Claims of the '013 Patent</p>	<p>SmartCuffs® 3.0</p>
	 <p>The image shows a black SmartCuffs 3.0 device with a color LCD screen. The screen displays 'SMART CUFFS' at the top, a battery level indicator, and a red-bordered box containing the text 'Pressure: 64 mmHg'. Below this, it says 'Disconnect Hose and Begin Exercise'. There are two main menu options: 'Repeat Pressure' and 'Start New Session'. At the bottom of the screen, there are three navigation buttons labeled 'Up/Home', 'Enter', and 'Down', along with a power button icon.</p>
<p>Claim 14</p>	<p><i>SmartCuffs 3.0 is an apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff.</i></p>
<p>14. An apparatus for personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on a personalized restrictive pressure (PRP), comprising:</p>	 <p>The image displays the SmartCuffs 3.0 apparatus against a black background. On the left, there are two dark-colored, cylindrical cuff components stacked vertically. Each cuff has a silver-colored sensor or port on its side. In the center is the main SmartCuffs 3.0 device, which is a light grey or white rectangular unit with a screen and several buttons. To the right of the device is a black coiled hose with a metal fitting at the end.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024).</p>

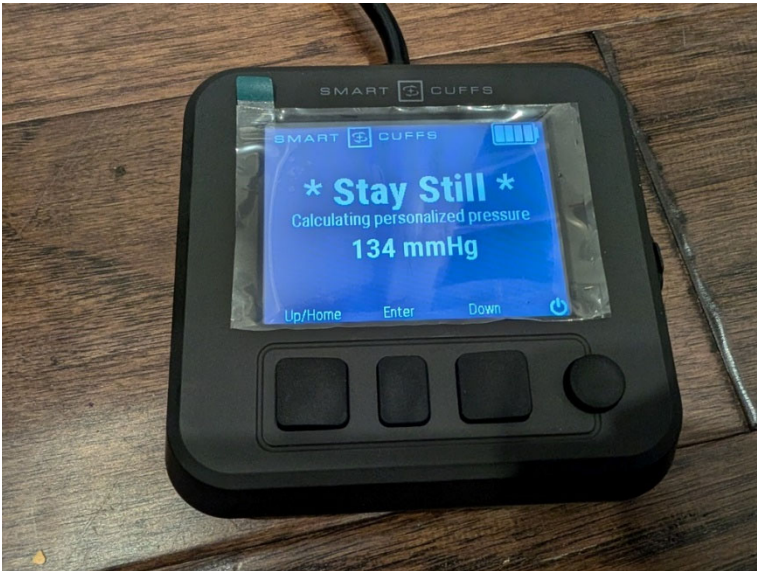
Claims of the '013 Patent	SmartCuffs® 3.0
	<p>What is Blood Flow Restriction Training?</p> <p>To improve muscular strength and size it has been assumed heavy loads must be lifted. Unfortunately, in certain populations, like older individuals, post-operative patients, or those rehabilitating an injury, high-load exercises can cause injury and not be tolerated.</p> <p>Blood Flow Restriction (BFR) training is a technique in which combines low-intensity exercise under reduced arterial flow conditions. BFR is quantifiably and objectively reducing the amount of blood flow into an extremity by using a specially made medical tourniquet. BFR allows individuals to use low loads yet achieve results similar to high intensity training.</p> <p>Blood Flow Restriction (BFR) Training</p> <p>BFR training was initially developed in the 1960s in Japan and known as KAATSU training.¹</p> <p>Â BFR involves the application of a pneumatic cuff (tourniquet) to the upper arms or the upper legs. BFR can be applied to either one or two of the upper or lower extremities at a time but never all four limbs at one time. <u>The cuff is then inflated to a specific pressure with the aim of obtaining partial arterial restriction and complete venous occlusion.</u> The client is then asked to perform resistance exercises at a low intensity of 20-30% of 1 repetition max (1RM), with high repetitions per set (15-30) and short rest intervals between sets (30 seconds). (2) There are non-exercising protocols for bone healing, recovery and high intensity exercise preparation.Â For example, for bicep curls one can use very light dumbbells (like 2.5 or 5lb weights) with the cuffs and still gain strength and size.Â</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p> <p><i>SmartCuffs 3.0 provides personalized restriction of blood flow into a limb and penetration past a tourniquet cuff based on personalized restrictive pressure (PRP).</i></p> <p> Personalized Pressure feature: This feature allows for a fast, hassle-free personalized pressure calculation. <u>With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. This unit will do everything for you.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>


Claims of the '013 Patent	SmartCuffs® 3.0
<p>a dual-purpose tourniquet cuff having a single inflatable bladder adapted to encircle a limb;</p>	<p><i>SmartCuffs 3.0 is a dual-purpose tourniquet cuff having a single inflatable bladder that is adapted to encircle a limb.</i></p>  <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024).</p> <p>APPLYING THE SMARTCUFFS</p> <p>APPLYING THE ARM CUFF</p>  <ol style="list-style-type: none"> 1 Apply cuff with the logo readable with valve on the outside of arm. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper arm. The bottom flap of the cuff should slide under the top part of the cuff. 2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard. 3 You are ready to begin to operate the SmartCuffs device. <p><i>*To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.</i></p>

Claims of the '013 Patent	SmartCuffs® 3.0
	<p data-bbox="634 317 1382 365"> For more detailed information, videos, and instruction, download our SmartCuffs® Academy app on the Apple App Store or Google Play Store.</p> <p data-bbox="461 407 716 428">APPLYING THE LEG CUFF</p> <div data-bbox="467 451 906 856"></div> <ol data-bbox="943 451 1393 779" style="list-style-type: none">1 Apply cuff with the logo readable with valve on the outside of leg. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper leg. The bottom flap of the cuff should slide under the top part of the cuff.2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard.3 You are ready to begin to operate the SmartCuffs device. <p data-bbox="971 810 1393 926"><i>*To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.</i></p> <p data-bbox="505 961 1344 1031">See https://www.smarttoolsplus.com/images/store/bfr%20user%20manual%202021%20low21.pdf (last accessed November 5, 2024).</p> <div data-bbox="467 1052 1300 1612"><p data-bbox="467 1136 683 1220">single inflatable bladder</p></div>

Claims of the '013 Patent	SmartCuffs® 3.0
	 <p>A photograph of the SmartCuffs 3.0 device, which is a grey, rectangular control unit with several buttons on top. A black, knitted fabric cuff is attached to the side. A red arrow points from a text box labeled "single inflatable bladder" to the cuff.</p>
<p>a controller selectively operating the inflatable bladder of the dual-purpose tourniquet cuff, the controller executing instructions to control:</p>	<p><i>SmartCuffs 3.0 has a controller that selectively operates the inflatable bladder of the tourniquet cuff and executes instructions to control the sensor module, a PRP estimator, and an effector module.</i></p>  <p>A photograph showing the internal components of the SmartCuffs 3.0 device. A green printed circuit board (PCB) is visible, featuring a central microcontroller chip, a yellow battery, and various electronic components. A red arrow points from a text box labeled "controller" to the microcontroller chip. The PCB is labeled "SMARTTOOLS" and "REV 8 10/16/23".</p>

Claims of the '013 Patent	SmartCuffs® 3.0
<p>a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose tourniquet cuff for measuring pressure pulsations to characterize a limb occlusion pressure (LOP), thereby to identify a minimum pressure at which arterial blood penetration past the cuff is stopped; and</p>	<p>SmartCuffs 3.0 has a sensor module with a pulsation sensor that communicates pneumatically with the inflatable bladder for measuring pressure pulsations.</p> <p> Personalized Pressure feature: This feature allows for a fast, hassle-free personalized pressure calculation. <u>With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. This unit will do everything for you.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>  <p>The sensor module characterizes limb occlusion pressure (LOP) to identify a minimum pressure at which arterial blood penetration past the cuff is stopped.</p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p><u>A Doppler ultrasound can be used to determine the blood flow to the limb. Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff.A The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculatedA by the SmartCuffs BFR cuffA as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are Å exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>

<p>Claims of the '013 Patent</p>	<p align="center">SmartCuffs® 3.0</p>
	<p>WHAT IS LIMB OCCLUSION PRESSURE & UPPER OPERATIONAL PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is then calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%–80%. Personalized Pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. <u>By establishing a baseline UOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? Personalized Pressure should be measured every 2–4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>WITH THIS SMARTCUFFS DEVICE, WE USE THE FOLLOWING INTENSITY LEVELS TO CORRESPOND TO UOP%:</p> <p>FOR THE ARM* Low = 30% UOP, Medium = 40% UOP, and High = 50% UOP FOR THE LEG* Low = 50% UOP, Medium = 65% UOP, and High = 80% UOP</p> <p><small>*Operating UOP tolerance +/-15mmHg</small></p> <p>See https://www.smarttoolsplus.com/images/store/bfr%20user%20manual%202021%20low21.pdf (last accessed November 5, 2024) (annotated).</p> 

Claims of the '013 Patent	SmartCuffs® 3.0
<p>a PRP estimator responsive to the sensor module for producing an estimate of a PRP, wherein the estimate of the PRP is less than the LOP and indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.</p>	<p><i>SmartCuffs 3.0 has a PRP estimator responsive to the sensor module for producing an estimate of a PRP, which is less than the LOP and is indicative of a level of pressure in the inflatable bladder that restricts but does not stop arterial blood penetration past the cuff.</i></p> <p> Personalized Pressure feature: This feature allows for a fast, hassle-free personalized pressure calculation. With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body. There is no need for an external doppler probe or hand pump. This unit will do everything for you.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/398/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p>A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p>WHAT IS LIMB OCCLUSION PRESSURE & UPPER OPERATIONAL PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is then calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%. Personalized Pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. By establishing a baseline UOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? Personalized Pressure should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>WITH THIS SMARTCUFFS DEVICE, WE USE THE FOLLOWING INTENSITY LEVELS TO CORRESPOND TO UOP%:</p> <p>FOR THE ARM* Low = 30% UOP, Medium = 40% UOP, and High = 50% UOP FOR THE LEG* Low = 50% UOP, Medium = 65% UOP, and High = 80% UOP</p> <p><small>*Operating UOP tolerance +/-15mmHg</small></p> </div>

Claims of the '013 Patent	SmartCuffs® 3.0
	<p>See https://www.smarttoolsplus.com/images/store/bfr%20user%20manual%202021%20low21.pdf (last accessed November 5, 2024) (annotated).</p> <div style="display: flex; justify-content: space-around;">   </div>

34. Accordingly, Defendant has been and still is directly infringing at least claims 1 and 14 of the '013 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §271 by making (or having made), using, selling, offering for sale, and/or importing in the United States the Accused Products.

35. On information and belief, Defendant has had knowledge of the '013 patent based on the marking of products on the website of WCE's licensee, Delfi, which are covered by one or more claims of the '013 patent. See <https://www.delfimedical.com/patents/> (last accessed November 5, 2024).

36. Moreover, Defendant had knowledge of U.S. Patent No. 10,646,232 ("the '232 patent"), which reissued as the '013 patent, by at least September 23, 2021, the date a letter was sent to Defendant indicating that Defendant infringes the claims of the '232 patent.

37. Defendant will continue to directly and indirectly infringe, literally and under the doctrine of equivalents, unless enjoined by this Court.

38. As a result of Defendant's infringement of the '013 patent, Plaintiff has suffered monetary damages, including without limitation lost profits and licensing royalties, in an amount not yet determined, has suffered irreparable harm and will continue to suffer irreparable harm in the future unless Defendant's infringing activities are enjoined by this Court.

39. Plaintiff will be greatly and irreparably harmed until Defendant and their agents, servants, employees, attorneys, representatives, and all others acting on their behalf are enjoined by this Court from infringing the '013 patent, and thus, Plaintiff is without an adequate remedy at law.

40. Despite having knowledge of the '013 patent and the technology it covers, Defendant continues to sell the Accused Products. Defendant's conduct toward Plaintiff in connection with its deliberate disregard of the '013 patent was and continues to be egregious.

41. Thus, Defendant's infringement of the '013 patent, which is entitled to a statutory presumption of validity under 35 U.S.C. § 282, has been and continues to be deliberate and willful.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 10,646,231

42. Plaintiff incorporates by reference the allegations in Paragraphs 1-41 of this Complaint as if fully set forth herein.

43. The '231 patent is in effect and is presumed valid under the Patent Laws of the United States.

44. On information and belief, Defendant has infringed and is infringing at least one claim of the '231 patent under 35 U.S.C. §271 by making (or having made), using, offering for sale, selling, and/or importing in the United States, without authority, the SmartCuffs® 4.0 and SmartCuffs® 3.0 Pro.

45. Claim 1 of the '231 patent recites as follows:

An apparatus for intermittent vascular occlusion based on a personalized tourniquet pressure (PTP), comprising:

a dual-purpose tourniquet cuff having an inflatable bladder adapted to encircle a portion of a patient;

a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose cuff for sensing and characterizing pressure pulsations indicative of a distal occlusion pressure (DOP), thereby to identify a minimum pressure at which penetration of blood past the cuff is stopped;


a PTP estimator responsive to the pulsation sensor for producing an estimate of a PTP, wherein the estimate of the PTP is a function of the DOP;

an effector module communicating pneumatically with the inflatable bladder of the dual-purpose cuff for maintaining pressure in the bladder near the PTP during a first time period and for maintaining pressure in the bladder near a second level of pressure during a second time period; and

a controller selectively operating the inflatable bladder in conjunction with the sensor module and the effector module.

46. On information and belief, Defendant has made, used, imported, sold, and/or offered to sell the SmartCuffs[®] 4.0. The claim chart below shows how at least independent claim 1 of the '231 patent reads on the SmartCuffs[®] 4.0, based on information currently available to Plaintiff and their attorneys. This claim chart is not intended to limit the scope of Plaintiff's infringement claim in any way and is intended to be without prejudice to Plaintiff's ability to assert different or additional claims of the '231 patent against Defendant and/or to apply such claims to the SmartCuffs[®] 4.0 differently in view of additional information that Plaintiff and their attorneys may acquire during the course of this litigation.

47. The SmartCuffs[®] 4.0 meets each element of claim 1 of the '231 patent:

Claim 1 of the '231 Patent	SmartCuffs® 4.0
<p>1. An apparatus for intermittent vascular occlusion based on a personalized tourniquet pressure (PTP), comprising:</p>	<p><i>SmartCuffs 4.0 is an apparatus for intermittent vascular occlusion based on a personalized tourniquet pressure (PTP).</i></p>  <p>See https://www.smarttoolsplus.com/smartcuffs/products/ (last accessed November 5, 2024).</p> <p>What is Blood Flow Restriction Training?</p> <p>To improve muscular strength and size it has been assumed heavy loads must be lifted. Unfortunately, in certain populations, like older individuals, post-operative patients, or those rehabilitating an injury, high-load exercises can cause injury and not be tolerated.</p> <p>Blood Flow Restriction (BFR) training is a technique in which combines low-intensity exercise under reduced arterial flow conditions. BFR is quantifiably and objectively reducing the amount of blood flow into an extremity by using a specially made medical tourniquet. BFR allows individuals to use low loads yet achieve results similar to high intensity training.</p> <p>Blood Flow Restriction (BFR) Training</p> <p>BFR training was initially developed in the 1960s in Japan and known as KAATSU training.¹</p> <p>Â BFR involves the application of a pneumatic cuff (tourniquet) to the upper arms or the upper legs. BFR can be applied to either one or two of the upper or lower extremities at a time but never all four limbs at one time. The cuff is then inflated to a specific pressure with the aim of obtaining partial arterial restriction and complete venous occlusion. The client is then asked to perform resistance exercises at a low intensity of 20-30% of 1 repetition max (1RM), with high repetitions per set (15-30) and short rest intervals between sets (30 seconds). (2) There are non-exercising protocols for bone healing, recovery and high intensity exercise preparation.Â For example, for bicep curls one can use very light dumbbells (like 2.5 or 5lb weights) with the cuffs and still gain strength and size.Â</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>

SmartCuffs 4.0 provides intermittent vascular occlusion based on a personalized tourniquet pressure (PTP).

After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. This 4.0 model, with its AI-powered processor and proprietary LOP algorithms, makes it the most intelligent BFR cuff on the market today.

SmartCuffs® 4.0 Features:

Patent-pending iBFR™ LOP Calibration - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.

See <https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/> (last accessed November 5, 2024) (annotated).

Exclusive Tri-Pressure™ Technology - As BFR research has evolved, so has the way clinicians and patients optimally use and program blood flow restriction training. Three distinct BFR modes that have shown to be highly effective are now at your fingertips.

Continuous BFR

- The cuffs are inflated during the exercise set and rest sessions.
- This will fatigue your muscles at a higher rate.
- Ideal for advanced rehab or de-loading joints.

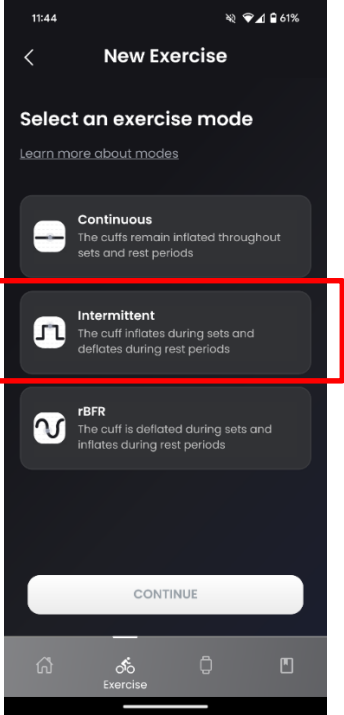

Intermittent BFR

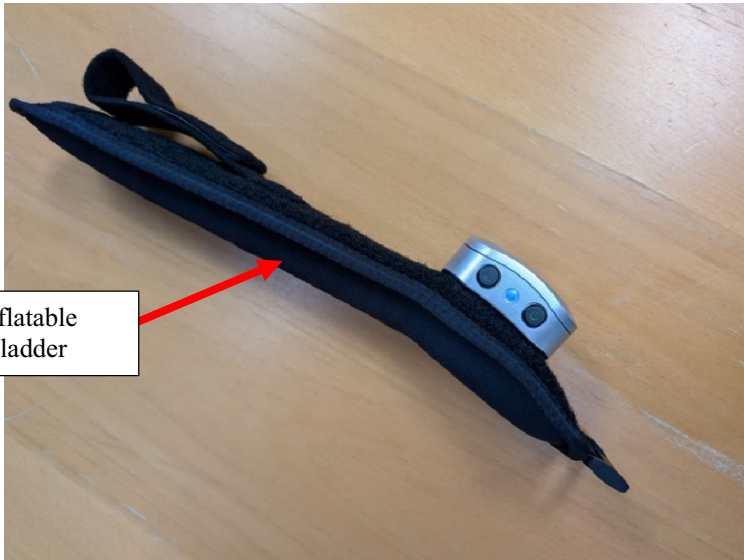
- The cuffs are only inflated only during the exercise session. Deflate during rest session.
- Ideal for beginner rehab or de-loading joints.


Resting BFR

- The cuffs are not inflated during the exercise session. Cuffs are only to be inflated during the rest session.
- Ideal for beginner rehab to ease into BFR training (using very light weight) or advanced rehab (using heavier weight).

See <https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/> (last accessed November 5, 2024) (annotated).

<p>Claim 1 of the '231 Patent</p>	<p align="center">SmartCuffs® 4.0</p>
	 <p>The screenshot shows a mobile application interface titled "New Exercise". It prompts the user to "Select an exercise mode" and lists three options: "Continuous", "Intermittent", and "rBFR". The "Intermittent" option, which states "The cuff inflates during sets and deflates during rest periods", is highlighted with a red rectangular box. A "CONTINUE" button is visible at the bottom of the selection screen.</p>
<p>a dual-purpose tourniquet cuff having an inflatable bladder adapted to encircle a portion of a patient;</p>	<p><i>SmartCuffs 4.0 is a dual-purpose tourniquet cuff having an inflatable bladder that is adapted to encircle a portion of a patient.</i></p>  <p>The image shows a black, fabric-based cuff with a white, rectangular control unit attached to the front. The control unit features a circular logo with a stylized 'S' and a star-like symbol. The cuff has adjustable straps and a textured interior lining.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024).</p>

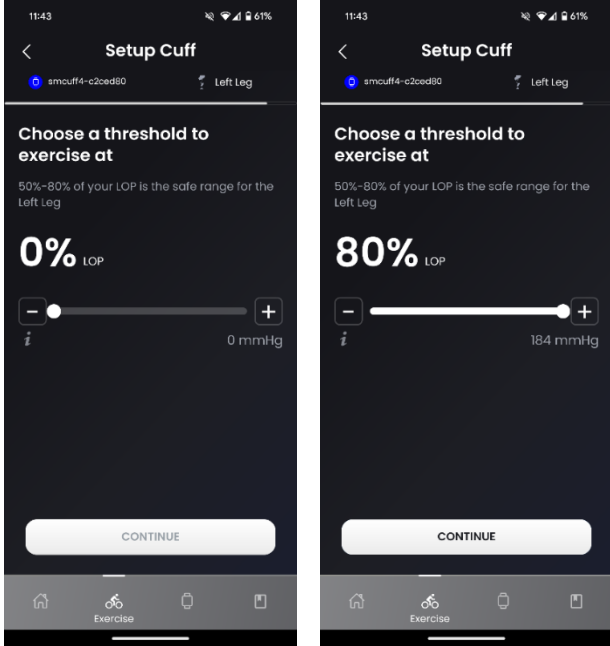
Claim 1 of the '231 Patent	SmartCuffs® 4.0
	<p data-bbox="451 296 1003 331">APPLYING THE SMARTCUFFS</p> <p data-bbox="610 436 889 464">APPLYING THE ARM CUFF</p> <ol data-bbox="610 478 1235 716" style="list-style-type: none"><li data-bbox="610 478 1235 604">1 <u>Apply cuff with the buttons/LED light facing up with the housing situated on the outside of arm. Push the strap of the cuff through plastic Strap Loop. Apply as tight as possible to the upper arm. The bottom flap of the cuff should slide under the top part of the cuff.</u><li data-bbox="610 621 1235 669">2 Connect the SmartCuffs 4.0 device to the SmartCuffs app via Bluetooth.<li data-bbox="610 686 1235 716">3 You are ready to begin to operate the SmartCuffs 4.0 device. <p data-bbox="646 732 1224 781"><i>*To release air from the cuff in case of emergency, press down on the Emergency Air Release Button (location on page 8).</i></p> <p data-bbox="435 877 1409 949">See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p>  <p data-bbox="467 1255 688 1335">inflatable bladder</p>

<p>Claim 1 of the '231 Patent</p>	<p>SmartCuffs® 4.0</p>
	 <p>A photograph of the SmartCuffs 4.0 cuff, which is a dark grey fabric cuff with a textured inner lining. A red arrow points from a white box labeled "inflatable bladder" to the inner lining of the cuff.</p>
<p>a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose cuff for sensing and characterizing pressure pulsations indicative of a distal occlusion pressure (DOP), thereby to identify a minimum pressure at which penetration of blood past the</p>	<p><i>SmartCuffs 4.0 has a sensor module with a pulsation sensor that communicates pneumatically with the inflatable bladder for sensing and characterizing pressure pulsations.</i></p> <div data-bbox="526 989 1289 1509"> <p>SPECIFICATIONS</p>  <p>The diagram shows two views of the sensor module. The left view shows the front panel with three buttons: a red "Emergency Air Release Button", a blue "Bluetooth LED Indicator", and a green "Power Button". The right view shows the back of the module with a "Strap Loop" and a "Pump Housing" which has a circular logo with a crosshair.</p> </div> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024).</p>


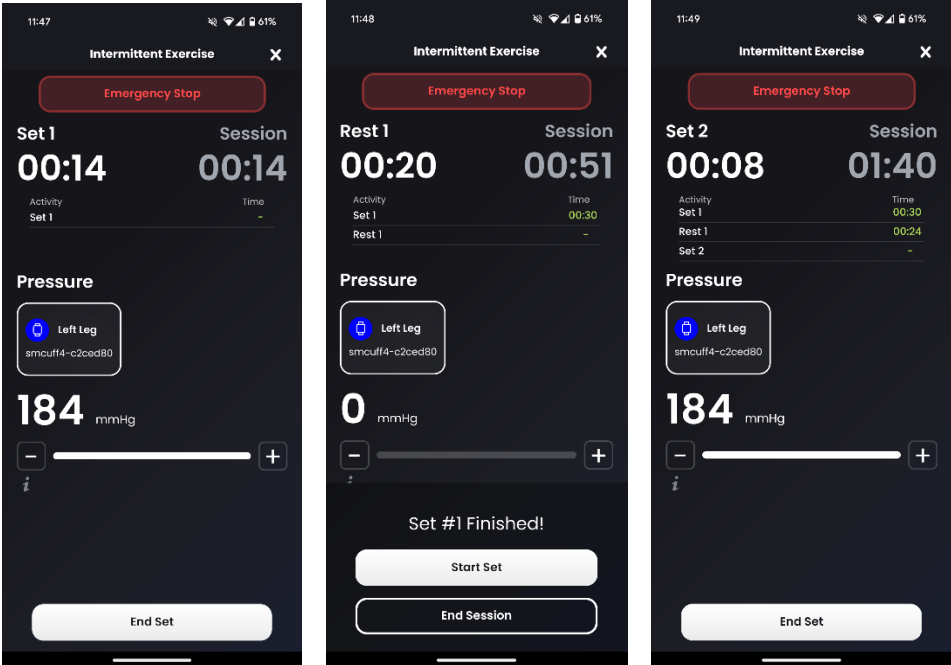
Claim 1 of the '231 Patent	SmartCuffs® 4.0
<p>cuff is stopped;</p>	<div data-bbox="641 283 1209 1039" data-label="Image"> </div> <p data-bbox="423 1052 1416 1161"><i>The pressure pulsations sensed and characterized by the sensor module are indicative of a distal occlusion pressure (DOP) to identify a minimum pressure at which penetration of blood past the cuff is stopped.</i></p> <p data-bbox="451 1188 1349 1325">After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. <u>This 4.0 model, with its AI-powered processor and proprietary LOP algorithms,</u> makes it the most intelligent BFR cuff on the market today.</p> <p data-bbox="451 1396 808 1428">SmartCuffs® 4.0 Features:</p> <p data-bbox="451 1478 1349 1577"><u>Patent-pending iBFR™ LOP Calibration - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. <u>By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></u></p> <p data-bbox="467 1617 1377 1686">See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>

Claim 1 of the '231 Patent	SmartCuffs® 4.0
	<p data-bbox="440 302 1235 342">WHAT IS LIMB OCCLUSION PRESSURE?</p> <p data-bbox="610 401 1289 632"><u>Limb Occlusion Pressure (LOP) is the amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe</u></p> <p data-bbox="435 688 1409 762">See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p> <div data-bbox="444 779 1401 1451"> </div>

<p>Claim 1 of the '231 Patent</p>	<p>SmartCuffs® 4.0</p>
<p>a PTP estimator responsive to the pulsation sensor for producing an estimate of a PTP, wherein the estimate of the PTP is a function of the DOP;</p>	<p><i>SmartCuffs 4.0 has a PTP estimator responsive to the sensor for producing an estimate of a PTP, which is a function of the DOP.</i></p> <p>After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. This 4.0 model, with its <u>AI-powered processor and proprietary LOP algorithms</u>, makes it the most intelligent BFR cuff on the market today.</p> <p>SmartCuffs® 4.0 Features:</p> <p><u>Patent-pending iBFR™ LOP Calibration</u> - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. <u>By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p> <p>WHAT IS LIMB OCCLUSION PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is the amount of pressure needed to occlude arterial blood flow.</u> This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. <u>BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe</u></p> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p>

Claim 1 of the '231 Patent	SmartCuffs® 4.0
	
<p>an effector module communicating pneumatically with the inflatable bladder of the dual-purpose cuff for maintaining pressure in the bladder near the PTP during a first time period and for maintaining pressure in the bladder near a second level of pressure during a second time period; and</p>	<p><i>SmartCuffs 4.0 has an effector module that communicates pneumatically with the inflatable bladder of the tourniquet cuff for maintaining pressure in the inflatable bladder near the PTP.</i></p> <p>After making the SmartCuffs® 3.0 the most popular BFR product in the world, we are upping the ante. <u>This 4.0 model, with its AI-powered processor and proprietary LOP algorithms,</u> makes it the most intelligent BFR cuff on the market today.</p> <p>SmartCuffs® 4.0 Features:</p> <p>Patent-pending iBFR™ LOP Calibration - Our clinically validated LOP calibration is back and better than ever. Finding LOP in as little as 10 seconds by utilizing our groundbreaking proprietary algorithms, it is the fastest and most comfortable LOP calibration process available. <u>By taking a percentage of LOP, the user can objectively know how much they are restricting blood flow for their given body structure. This is critical since LOP's vary wildly from person to person. This takes out all the guessing for a truly easy and quick experience.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>

<p>Claim 1 of the '231 Patent</p>	<p align="center">SmartCuffs® 4.0</p>
	<p>WHAT IS LIMB OCCLUSION PRESSURE?</p> <p><u>Limb Occlusion Pressure (LOP) is the amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe</u></p> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024) (annotated).</p> <p><i>The effector module maintains pressure in the bladder near the PTP during a first time period and maintains pressure in the bladder near a second level of pressure during a second time period.</i></p> <p>Exclusive Tri-Pressure™ Technology - As BFR research has evolved, so has the way clinicians and patients optimally use and program blood flow restriction training. Three distinct BFR modes that have shown to be highly effective are now at your fingertips.</p> <p>Continuous BFR</p> <ul style="list-style-type: none"> • The cuffs are inflated during the exercise set and rest sessions. • This will fatigue your muscles at a higher rate. • Ideal for advanced rehab or de-loading joints. <div style="border: 1px solid red; padding: 5px;"> <p>Intermittent BFR</p> <ul style="list-style-type: none"> • The cuffs are only inflated only during the exercise session. Deflate during rest session. • Ideal for beginner rehab or de-loading joints. </div> <div style="border: 1px solid red; padding: 5px; margin-top: 10px;"> <p>Resting BFR</p> <ul style="list-style-type: none"> • The cuffs are not inflated during the exercise session. Cuffs are only to be inflated during the rest session. • Ideal for beginner rehab to ease into BFR training (using very light weight) or advanced rehab (using heavier weight). </div> <p>See https://www.smarttoolsplus.com/detail.cfm/id/527/name/smartcuffs/ (last accessed November 5, 2024) (annotated).</p>


Claim 1 of the '231 Patent	SmartCuffs® 4.0
	 <p>The photograph shows the internal components of the SmartCuffs 4.0 device. A yellow rectangular box highlights a specific area containing a small metal component and a clear plastic tube. A red arrow points from a white box labeled "effector module" to this highlighted area. To the right of the highlighted area is a large, rectangular, silver-colored battery with the text "TSMC Cell 102050 3.7V 1000mAh" printed on it. The device is held open, revealing the internal circuitry and components.</p>  <p>The three screenshots show the mobile application interface for the SmartCuffs 4.0 device. Each screenshot displays the "Intermittent Exercise" screen with an "Emergency Stop" button at the top. The first screenshot shows "Set 1" with a duration of 00:14 and a session time of 00:14. The pressure reading is 184 mmHg. The second screenshot shows "Rest 1" with a duration of 00:20 and a session time of 00:51. The pressure reading is 0 mmHg. The third screenshot shows "Set 2" with a duration of 00:08 and a session time of 01:40. The pressure reading is 184 mmHg. Each screenshot also includes a pressure control slider and buttons for "End Set" or "End Session".</p>



Claim 1 of the '231 Patent	SmartCuffs® 4.0
<p>a controller selectively operating the inflatable bladder in conjunction with the sensor module and the effector module.</p>	<p><i>SmartCuffs 4.0 has a controller that selectively operates the inflatable bladder in conjunction with the sensor module and the effector module.</i></p> <div data-bbox="526 373 1289 890" style="text-align: center;"> <p>SPECIFICATIONS</p> </div> <p>See https://www.smarttoolsplus.com/wp-content/uploads/2023/05/bfr-4.0-user-manual-2023-v2.pdf (last accessed November 5, 2024).</p> <div data-bbox="542 999 1393 1371" style="text-align: center;"> </div>

48. On information and belief, Defendant has made, used, imported, sold, and/or offered to sell the SmartCuffs® 3.0 Pro. The claim chart below shows how at least independent claim 1 of the '231 patent reads on the SmartCuffs® 3.0 Pro, based on information currently available to Plaintiff and their attorneys. This claim chart is not intended to limit the scope of Plaintiff's infringement claim in any way and is intended to be without prejudice to Plaintiff's ability to assert different or additional claims of the '231 patent against Defendant and/or to

apply such claims to the SmartCuffs® 3.0 Pro differently in view of additional information that Plaintiff and their attorneys may acquire during the course of this litigation.

49. The SmartCuffs® 3.0 Pro meets each element of claim 1 of the '231 patent:

Claim 1 of the '231 Patent	SmartCuffs® 3.0 Pro
<p>1. An apparatus for intermittent vascular occlusion based on a personalized tourniquet pressure (PTP), comprising:</p>	<p><i>SmartCuffs 3.0 Pro is an apparatus for intermittent vascular occlusion based on a personalized tourniquet pressure (PTP).</i></p>  <p>See https://www.smarttoolsplus.com/smartcuffs/products/ (last accessed November 5, 2024).</p> <p>What is Blood Flow Restriction Training?</p> <p>To improve muscular strength and size it has been assumed heavy loads must be lifted. Unfortunately, in certain populations, like older individuals, post-operative patients, or those rehabilitating an injury, high-load exercises can cause injury and not be tolerated.</p> <p>Blood Flow Restriction (BFR) training is a technique in which combines low-intensity exercise under reduced arterial flow conditions. BFR is quantifiably and objectively reducing the amount of blood flow into an extremity by using a specially made medical tourniquet. BFR allows individuals to use low loads yet achieve results similar to high intensity training.</p> <p>Blood Flow Restriction (BFR) Training</p> <p>BFR training was initially developed in the 1960s in Japan and known as KAATSU training.¹</p> <p><u>^ BFR involves the application of a pneumatic cuff (tourniquet) to the upper arms or the upper legs. BFR can be applied to either one or two of the upper or lower extremities at a time but never all four limbs at one time. The cuff is then inflated to a specific pressure with the aim of obtaining partial arterial restriction and complete venous occlusion. The client is then asked to perform resistance exercises at a low intensity of 20-30% of 1 repetition max (1RM), with high repetitions per set (15-30) and short rest intervals between sets (30 seconds). (2) There are non-exercising protocols for bone healing, recovery and high intensity exercise preparation.</u>^ For example, for bicep curls one can use very light dumbbells (like 2.5 or 5lb weights) with the cuffs and still gain strength and size.</p>

<p>Claim 1 of the '231 Patent</p>	<p align="center">SmartCuffs® 3.0 Pro</p>
	<p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p> <p><i>SmartCuffs 3.0 Pro provides intermittent vascular occlusion based on a personalized tourniquet pressure (PTP).</i></p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body. There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: <u>Built into the software, these modes can be easily performed pre & post activity by the user.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p> <p>Similarities</p> <p>Both are electronic, computerized, and will automatically calculate, set, and inflate to a personalized pressure.</p> <p>Both have the option to disconnect the hose from the cuffs for untethered exercise.</p> <p>Differences</p> <p>The PRO pump also allows custom personal pressure selection whereas the regular model (\$299-\$399) will offer preset personal pressures according to an intensity level (Low, Medium, and High):</p> <p><u>SmartCuffs PRO has IPC (Ischemic Preconditioning) modes built into it. The regular model does not.</u></p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p> <p>WHAT IS IPC (ISCHEMIC PRECONDITIONING)?</p> <p>Ischemic preconditioning (IPC) is a therapeutic approach that has been developed to attenuate the damage incurred by ischemia-reperfusion injury.</p> <p><u>DO NOT EXERCISE OR MOVE DURING THIS MODE. THIS IS A PASSIVE MODALITY.</u></p> <p><u>Characterized by cyclical occlusion and reperfusion of the arms or legs,</u> this therapy has been used in numerous clinical trials in diverse patient populations, including patients undergoing repair of congenital heart defects, coronary artery bypass grafting, and primary percutaneous coronary intervention. <u>In BFR, we use 5 minutes of 80-100% occlusion with 5 minutes of free flow for 3-5 rounds then (within 45 minutes) perform high intensity exercises.</u> The IPC prior to high intensity exercise has been shown to attenuate exercise induced muscle damage.</p> <p>SAFETY DISCLAIMER IPC should only be done under the supervision and guidance of a medical professional at all times.</p> <p>See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024) (annotated).</p>

<p>Claim 1 of the '231 Patent</p>	<p align="center">SmartCuffs® 3.0 Pro</p>
<p>a dual-purpose tourniquet cuff having an inflatable bladder adapted to encircle a portion of a patient;</p>	<p><i>SmartCuffs 3.0 Pro is a dual-purpose tourniquet cuff having an inflatable bladder that is adapted to encircle a portion of a patient.</i></p> <div data-bbox="488 373 1360 1066" data-label="Image"> </div> <p>See https://www.smarttoolsplus.com/smartcuffs/products/ (last accessed November 5, 2024).</p> <div data-bbox="451 1188 976 1228" data-label="Section-Header"> <h2>APPLYING THE SMARTCUFFS</h2> </div> <div data-bbox="451 1276 717 1304" data-label="Section-Header"> <h3>APPLYING THE ARM CUFF</h3> </div> <div data-bbox="451 1325 899 1730" data-label="Image"> </div> <div data-bbox="927 1318 1382 1650" data-label="List-Group"> <ol style="list-style-type: none"> 1 Apply cuff with the logo readable with valve on the outside of arm. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper arm. The bottom flap of the cuff should slide under the top part of the cuff. 2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard. 3 You are ready to begin to operate the SmartCuffs PRO device. </div> <div data-bbox="954 1677 1382 1793" data-label="Text"> <p><i>*To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.</i></p> </div>

Claim 1 of the '231 Patent

SmartCuffs® 3.0 Pro



For more detailed information, videos, and instruction, download our SmartCuffs® Academy app on the Apple App Store or Google Play Store.

APPLYING THE LEG CUFF






- 1 Apply cuff with the logo readable with valve on the outside of leg. Push the strap of the cuff through plastic D-ring (#9). Apply as tight as possible to the upper leg. The bottom flap of the cuff should slide under the top part of the cuff.
- 2 Attach the coupler (#6) by pushing down on the metal pin. You should hear a click. If no click is heard, the pin is already in position. Attach coupler into valve. A click will be heard.
- 3 You are ready to begin to operate the SmartCuffs PRO device.

**To release air from the cuff in case of emergency, press down on the Air Release Port (#12) without covering the port entirely (or else you will block the escaping air). If this does not work, simply take the cuff off by releasing from the Velcro.*

See <https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf> (last accessed November 5, 2024).

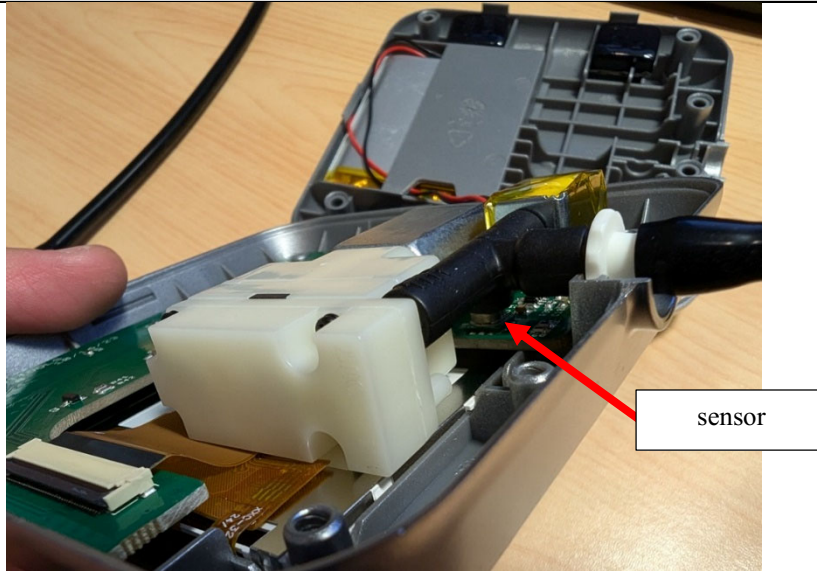
inflatable bladder



<p>Claim 1 of the '231 Patent</p>	<p>SmartCuffs® 3.0 Pro</p>
	
<p>a sensor module having a pulsation sensor communicating pneumatically with the inflatable bladder of the dual-purpose cuff for sensing and characterizing pressure pulsations indicative of a distal occlusion pressure (DOP), thereby to identify a minimum pressure at which penetration of blood past the cuff is stopped;</p>	<p><i>SmartCuffs 3.0 Pro has a sensor module with a pulsation sensor that communicates pneumatically with the inflatable bladder for sensing and characterizing pressure pulsations.</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the <u>built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p>

**Claim 1 of the
'231 Patent**

SmartCuffs® 3.0 Pro



The pressure pulsations sensed and characterized by the sensor module are indicative of a distal occlusion pressure (DOP) to identify a minimum pressure at which penetration of blood past the cuff is stopped.

BFR CUFF PRESSURE

There are different methods to determine proper BFR cuff pressures.

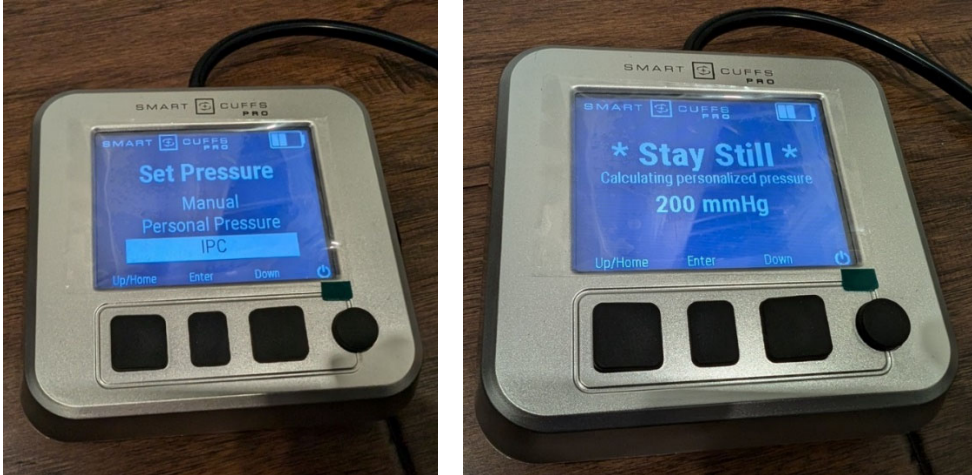
A Doppler ultrasound can be used to determine the blood flow to the limb. Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.



Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)


The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.



The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)

See <https://www.smarttoolsplus.com/resources/what-is-bfr/> (last accessed November 5, 2024) (annotated).

Claim 1 of the '231 Patent	SmartCuffs® 3.0 Pro
	<p>WHAT IS LIMB OCCLUSION PRESSURE (LOP)?</p> <p><u>Limb Occlusion Pressure (LOP) is the minimal amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? LOP/"Personalized Pressure" should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>RECOMMENDED % OF LOP:</p> <p>FOR THE ARM* 30%-50% LOP FOR THE LEG* 50%-80% LOP</p> <p><i>*Operating LOP tolerance +/- 15mmHg</i></p> <p>See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024) (annotated).</p> 

Claim 1 of the '231 Patent	SmartCuffs® 3.0 Pro
<p>a PTP estimator responsive to the pulsation sensor for producing an estimate of a PTP, wherein the estimate of the PTP is a function of the DOP;</p>	<p><i>SmartCuffs 3.0 Pro has a PTP estimator responsive to the sensor for producing an estimate of a PTP, which is a function of the DOP.</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the <u>built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p>A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>

<p>Claim 1 of the '231 Patent</p>	<p align="center">SmartCuffs® 3.0 Pro</p>
	<p align="center">WHAT IS LIMB OCCLUSION PRESSURE (LOP)?</p> <p><u>Limb Occlusion Pressure (LOP) is the minimal amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.</u></p> <p>HOW OFTEN SHOULD IT BE MEASURED? LOP/"Personalized Pressure" should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.</p> <p>RECOMMENDED % OF LOP: FOR THE ARM* 30%-50% LOP FOR THE LEG* 50%-80% LOP</p> <p align="center"><i>*Operating LOP tolerance +/- 15mmHg</i></p> <p align="center">See https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf (last accessed November 5, 2024) (annotated).</p> 

Claim 1 of the '231 Patent	SmartCuffs® 3.0 Pro
<p>an effector module communicating pneumatically with the inflatable bladder of the dual-purpose cuff for maintaining pressure in the bladder near the PTP during a first time period and for maintaining pressure in the bladder near a second level of pressure during a second time period; and</p>	<p><i>SmartCuffs 3.0 Pro has an effector module that communicates pneumatically with the inflatable bladder of the tourniquet cuff.</i></p> <p>The SmartCuffs® PRO model was designed with one person in mind: the healthcare professional. Whether you are a personal trainer, strength coach, or medical provider, this model was built with your needs in mind.</p> <p> Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the <u>built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body.</u> There is no need for an external doppler probe or hand pump. The unit will do everything for you.</p> <p> IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.</p> <p>See https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/ (last accessed November 5, 2024) (annotated).</p> <p>BFR CUFF PRESSURE</p> <p>There are different methods to determine proper BFR cuff pressures.</p> <p>A Doppler ultrasound can be used to determine the blood flow to the limb. <u>Limb Occlusion Pressure (LOP) is a pressure needed to occlude arterial blood flow. Upper Operational Pressure (UOP) is a maximum BFR cuff pressure determined for each user by the SmartCuffs BFR cuff. The UOP is a pressure that is slightly less than LOP. The UOP is used to account for pressure variances from user to user. A personalized pressure is calculated by the SmartCuffs BFR cuff as a percentage of the UOP, normally between 40%-80%.</u></p> <p>Using this method is preferable as it ensures patients are exercising at the correct pressure for them and the type of cuff being used. It is safer and makes sure that they are exercising at optimal pressures, not too high to cause tissue damage and also not too low to be ineffective. (4)</p> <p>The pressure of the cuff depends upon the width of the cuff as well as the size of the limb on which the cuff is applied.</p> <p>The key to BFR is that the pressure needs to be high enough to occlude venous return and allow blood pooling but needs to be low enough to maintain the arterial inflow. Perceived wrap tightness, on a scale of 0-10 has also been used to conduct BFR training. Wilson et al (2013) found that a perceived wrap tightness of 7 out of 10 resulted in total venous occlusion but still allowed arterial inflow. (5,6)</p> <p>See https://www.smarttoolsplus.com/resources/what-is-bfr/ (last accessed November 5, 2024) (annotated).</p>

**Claim 1 of the
'231 Patent**

SmartCuffs® 3.0 Pro

WHAT IS LIMB OCCLUSION PRESSURE (LOP)?

Limb Occlusion Pressure (LOP) is the minimal amount of pressure needed to occlude arterial blood flow. This is the gold standard being used to quantify the amount of pressure needed per user in BFR research. Personalized tourniquet pressure for each individual patient eliminates the need to account for cuff width, limb size, or blood pressure. BFR requires the reduction of arterial inflow and the elimination of venous outflow. By establishing a baseline LOP, we can know how much to reduce the pressure by so you are never exercising at occlusion, which is unsafe.

HOW OFTEN SHOULD IT BE MEASURED?

LOP/"Personalized Pressure" should be measured every 2-4 weeks. It does not need to be measured every session unless directed by your healthcare professional.

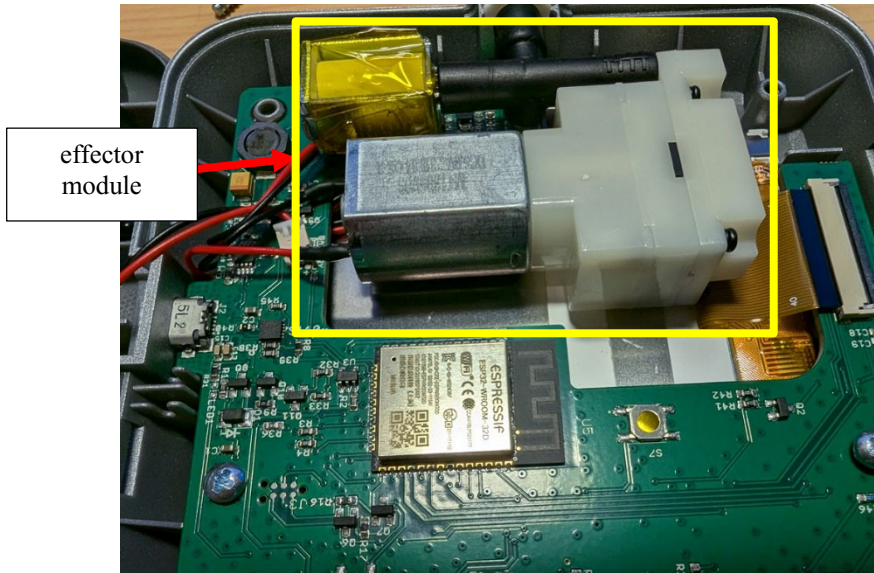
RECOMMENDED % OF LOP:

FOR THE ARM* 30%-50% LOP

FOR THE LEG* 50%-80% LOP

**Operating LOP tolerance +/- 15mmHg*

See <https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf> (last accessed November 5, 2024) (annotated).



The effector module maintains pressure in the bladder near the PTP during a first time period and maintains pressure in the bladder near a second level of pressure during a second time period.



Personalized Pressure feature: The same mode found in the standard model allows for fast, hassle free personalized pressure calculation. With the built-in pressure sensor and on-board computer, it will calculate and set the optimal pressure for your body. There is no need for an external doppler probe or hand pump. The unit will do everything for you.



IPC modes: Built into the software, these modes can be easily performed pre & post activity by the user.

See <https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/> (last accessed November 5, 2024) (annotated).

Similarities

Both are electronic, computerized, and will automatically calculate, set, and inflate to a personalized pressure.

Both have the option to disconnect the hose from the cuffs for untethered exercise.

Differences

The PRO pump also allows custom personal pressure selection whereas the regular model (\$299-\$399) will offer preset personal pressures according to an intensity level (Low, Medium, and High):

SmartCuffs PRO has IPC (Ischemic Preconditioning) modes built into it. The regular model does not.

See <https://www.smarttoolsplus.com/detail.cfm/id/400/name/smartcuffs-pro/> (last accessed November 5, 2024) (annotated).

WHAT IS IPC (ISCHEMIC PRECONDITIONING)?

Ischemic preconditioning (IPC) is a therapeutic approach that has been developed to attenuate the damage incurred by ischemia-reperfusion injury.

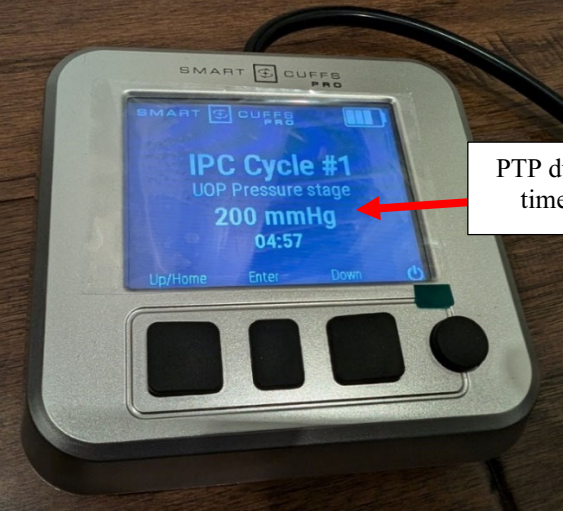
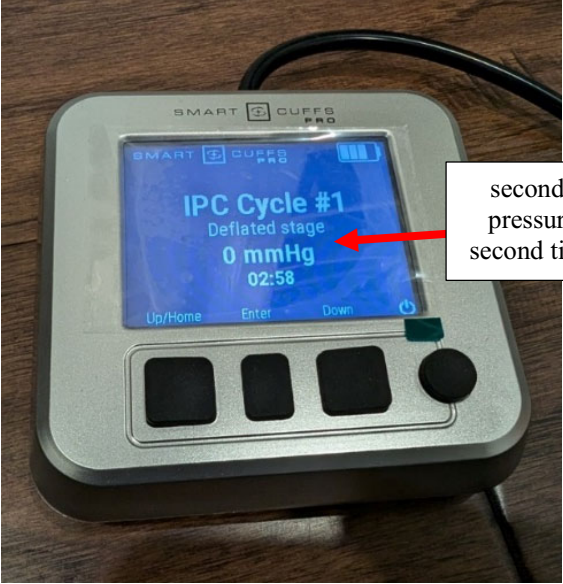
DO NOT EXERCISE OR MOVE DURING THIS MODE. THIS IS A PASSIVE MODALITY.

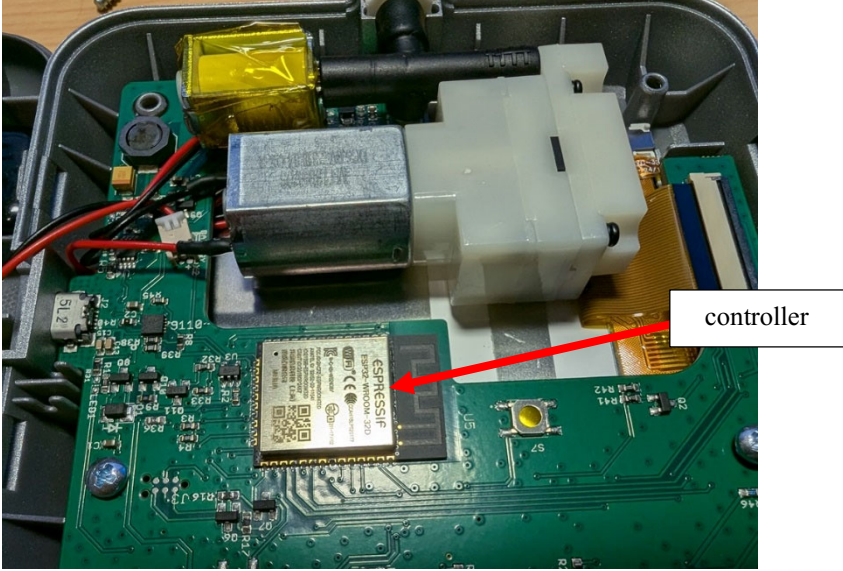
Characterized by cyclical occlusion and reperfusion of the arms or legs, this therapy has been used in numerous clinical trials in diverse patient populations, including patients undergoing repair of congenital heart defects, coronary artery bypass grafting, and primary percutaneous coronary intervention. In BFR, we use 5 minutes of 80-100% occlusion with 5 minutes of free flow for 3-5 rounds then (within 45 minutes) perform high intensity exercises. The IPC prior to high intensity exercise has been shown to attenuate exercise induced muscle damage.

SAFETY DISCLAIMER

IPC should only be done under the supervision and guidance of a medical professional at all times.

See <https://www.smarttoolsplus.com/images/store/smartcuffs%20pro%20user%20manual%20high%20res4.pdf> (last accessed November 5, 2024) (annotated).

Claim 1 of the '231 Patent	SmartCuffs® 3.0 Pro
	  <p>The image displays two sequential screenshots of the SmartCuffs 3.0 Pro device's LCD screen. The top screenshot shows the device in the 'UOP Pressure stage' of 'IPC Cycle #1' at a pressure of 200 mmHg with a timer of 04:57. A red arrow points from a callout box labeled 'PTP during first time period' to the 200 mmHg value. The bottom screenshot shows the device in the 'Deflated stage' of 'IPC Cycle #1' at a pressure of 0 mmHg with a timer of 02:58. A red arrow points from a callout box labeled 'second level of pressure during second time period' to the 0 mmHg value. Both screenshots show the device's control buttons (Up/Home, Enter, Down) and a power button below the screen.</p>

Claim 1 of the '231 Patent	SmartCuffs® 3.0 Pro
<p>a controller selectively operating the inflatable bladder in conjunction with the sensor module and the effector module.</p>	<p><i>SmartCuffs 3.0 Pro has a controller that selectively operates the inflatable bladder in conjunction with the sensor module and the effector module.</i></p> 

50. Accordingly, Defendant has been and still is directly infringing at least claim 1 of the '231 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §271 by making (or having made), using, selling, offering for sale, and/or importing in the United States the SmartCuffs® 4.0 and SmartCuffs® 3.0 Pro.

51. On information and belief, Defendant has had knowledge of the '231 patent based on the marking of products by WCE's licensee, Delfi, which are covered by one or more claims of the '231 patent. See <https://www.delfimedical.com/patents/> (last accessed November 5, 2024).

52. Moreover, Defendant had knowledge of the '231 patent by at least September 23, 2021, the date a letter was sent to Defendant indicating that Defendant infringes the claims of the '231 patent.

53. Defendant will continue to directly and indirectly infringe, literally and under the doctrine of equivalents, unless enjoined by this Court.

54. As a result of Defendant's infringement of the '231 patent, Plaintiff has suffered monetary damages, including without limitation lost profits and licensing royalties, in an amount not yet determined, has suffered irreparable harm and will continue to suffer irreparable harm in the future unless Defendant's infringing activities are enjoined by this Court.

55. Plaintiff will be greatly and irreparably harmed until Defendant and their agents, servants, employees, attorneys, representatives, and all others acting on their behalf are enjoined by this Court from infringing the '231 patent, and thus, Plaintiff is without an adequate remedy at law.

56. Despite having knowledge of the '231 patent and the technology it covers, Defendant continues to sell the SmartCuffs[®] 4.0 and SmartCuffs[®] 3.0 Pro. Defendant's conduct toward Plaintiff in connection with its deliberate disregard of the '231 patent was and continues to be egregious.

57. Thus, Defendant's infringement of the '231 patent, which is entitled to a statutory presumption of validity under 35 U.S.C. § 282, has been and continues to be deliberate and willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendant as follows:

- A. A judgment in favor of Plaintiff against Defendant;
- B. A judgment that Defendant has infringed and continues to infringe the claims of the '013 patent;
- C. A judgment that Defendant, its officers, agents, servants, employees, attorneys, and all other persons in active concert or participation with them, be preliminarily

- and permanently enjoined and restrained from further infringing the claims of the '013 patent during its term;
- D. A judgment against Defendant awarding Plaintiff damages suffered by Plaintiff in accordance with 35 U.S.C. § 284 on account of Defendant's infringement of the '013 patent;
- E. A judgment that Defendant has infringed and continues to infringe the claims of the '231 patent;
- F. A judgment that Defendant, its officers, agents, servants, employees, attorneys, and all other persons in active concert or participation with them, be preliminarily and permanently enjoined and restrained from further infringing the claims of the '231 patent during its term;
- G. A judgment against Defendant awarding Plaintiff damages suffered by Plaintiff in accordance with 35 U.S.C. § 284 on account of Defendant's infringement of the '231 patent;
- H. A declaration that this action is an exceptional case under 35 U.S.C. § 285 and an award to Plaintiff of its attorneys' fees incurred in filing this action; and
- I. Such other and further relief as this Court may deem just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests a trial by jury on all issues so triable.

Date: November 5, 2024

Respectfully submitted,

/s/ Todd R. Tucker

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