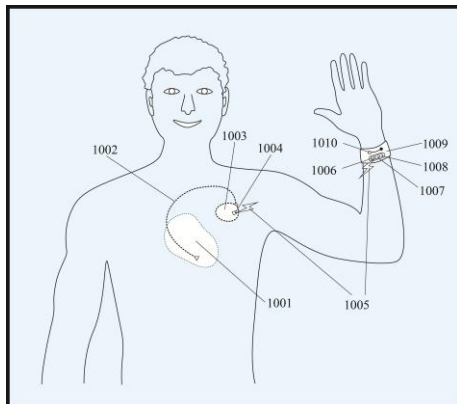




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Medibotics' Work Related to Circulatory Function: 8/29/2025



Medibotics is a small Minnesota company working to address significant clinical needs by innovating at the convergence of medical devices and wearable technology. One area of focus is the development of feedback-loop systems for circulatory function in which the operation of a cardiac pacemaker is automatically adjusted in response to biometric parameters which are measured by a device worn on a peripheral body location (such as a person's wrist, ear, arm, or leg). Such feedback-loop systems have the potential to improve circulatory function, maintain peripheral tissue health, and manage significant chronic conditions (such as congestive heart failure).

In an example, the pacing rate or stimulation magnitude of a cardiac pacemaker can be increased in response to low peripheral tissue oxygenation as measured by a wearable device on a person's arm, leg, or ear. In an example, the pacing rate or stimulation magnitude of a cardiac pacemaker can be decreased in response to high peripheral blood pressure measured by a wearable device on a person's arm, leg, or ear. In an example, a wearable device and a cardiac pacemaker can together comprise a closed loop system for cardiac rhythm management to address chronic heart conditions (such as congestive heart failure).

As one application, there is a need to adjust the rate of cardiac pacing based on changes in the oxygen requirements of a person's body due to changes in body motion and non-motion factors such as mental effort and emotional state (Dell'Orto et al., 2004; Lau et al., 2007). There is also a need to ensure that even the extremities of a person's body are receiving sufficient oxygen to maintain proper tissue health. Biometric sensors which have been used to adjust cardiac pacing include: motion sensors (e.g. accelerometers), minute ventilation sensors, and implanted oxygen level sensors.

There are limitations to using any of these types of sensors alone. Limitations of using an accelerometer alone (especially a single accelerometer in a person's torso) to adjust the rate of cardiac pacing include: low sensitivity to motion of body members in other locations (e.g. motion of legs during cycling when the accelerometer is within the person's torso); low sensitivity to changing requirements at high workloads and during recovery from exercise; and oxygen requirements of mental effort or emotional stress which do not involve body motion (Zweerink et al., 2018; Kneller, 2018; and Occhetta et al., 2011). Limitations of using a minute ventilation sensor alone to adjust the rate of cardiac pacing include: false positive reactions in hyperventilation; interference with posture; low reliability in patients with obstructive pulmonary disease; missing modest heart rate changes that may normally occur during a single respiratory cycle; over-sensing; and relatively slow response speed (Zweerink et al., 2018; Dell'Orto et al., 2004; Kneller, 2018; and Occhetta et al., 2011). Limitations of using an implanted oxygen level sensor alone to adjust the rate of cardiac pacing include: changing conditions of light reflection around an electrode; movement of erythrocytes with different oxygen saturation levels; incomplete mixing of blood; and variability in oxygen sensor position (Occhetta et al., 2011).

Combinations of different types of sensors, especially the combination an accelerometer and a minute ventilation sensor, can be superior to one type alone and have been incorporated into closed loop systems (CLS) for adjustable rate cardiac pacing (Abi-Samra et al., 2013; Anon, 2017a; Anon, 2017b; Cao et al., 2015; Chandiramani et al., 2007; Chinitz et al., 2016; Coenen et al., 2008; Coman et al., 2008; Kneller et

al., 2017; Lindovska et al., 2012; Occhetta et al., 2011; Paoletti et al., 2018; Pavri et al., 2006; Pilat et al., 2008; Proietti et al., 2012; Proietti et al., 2012; Quaglione et al., 2010; Richards et al., 2018; Wiegand et al., 2008).

However, even pacing systems which combine an accelerometer and minute ventilation sensor lack the finesse of a normal chronotropic response (Kneller, 2018). Also, centrally implanted sensors can be insensitive to variation in tissue oxygenation in body extremities. The accuracy and wearability of externally-worn biometric devices such as pulse oximetry and photoplethysmography (PPG) devices has improved during the past several years (Harju et al., 2018; Fridman et al., 2016). Incorporating data from one or more such externally-worn biometric devices can provide valuable (additional) data concerning tissue health (e.g. tissue oxygenation level) including that of body extremities which can help to overcome the limitations of implanted sensors for variable rate pacing. Further, cardiac pacing systems with multiple wearable devices at different body locations can provide information on area variation in oxygenation level which is not possible with a single centrally-located sensor.

In another application, a wearable device which is part of a feedback system for cardiac rhythm management can be a photoplethysmography (PPG) device. PPG is a method which analyzes periodic variation in the amount of light which is caused by reflection of the light from (or transmission of the light through) body tissue in order to measure one or more biometric parameters such as heart rate or heart rate variation. Changes in the shape of blood vessels in body tissue change the amount of light which is reflected from, or transmitted through, the body tissue.

Biometric information from a wearable photoplethysmography (PPG) device can be used to adjust the operation of an implanted device such as a cardiac pacemaker, creating a feedback loop or (in the extreme) a closed-loop system for improving cardiac function and peripheral tissue health. Measurement of one or more biometric parameters from one or more peripheral locations (such as a person's ears, fingers, or feet) can provide information on cardiac function and peripheral tissue health which is not available from a central location (such as a person's heart or abdomen). Together a wearable photoplethysmography (PPG) device and an implanted cardiac pacemaker can comprise a system for cardiac rhythm management and/or treating a heart-related condition.

The following is a list of Medibotics' IP for circulatory function, including cardiac rhythm management:

<p>U.S. Patent 12268883 (patented) "Integrated System to Assist Cardiovascular Functioning with Implanted Cardiac Device and Sensor-Enabled Wearable Device*" filed on 2021-08-24</p>	<p>Abstract: This invention is a system to assist human cardiovascular functioning which integrates the operation of an implanted cardiac device and a wearable device with an arcuate array of biometric sensors. Analysis of data from the biometric sensors on the wearable device is used to automatically adjust and optimize the operation of the implanted cardiac device. This system can work as a closed loop system for assisting and improving human cardiovascular functioning.</p>
<p>U.S. Patent Application Publication 20250161692 (pending) "System for Cardiac Rhythm Management Which Ensures Good Oxygenation of Body Extremities" filed on 2025-01-17</p>	<p>Abstract: Disclosed herein is a system for cardiac rhythm management including an implanted cardiac pacemaker and a biometric finger ring. This system ensures good oxygenation of a person's body extremities. The finger ring includes optical sensors which measure the person's blood oxygenation level. The operation of the implanted cardiac pacemaker is adjusted based on combined analysis of motion data from the pacemaker, motion data from the finger ring, and blood oxygenation level data from the biometric finger ring.</p>
<p>U.S. Patent Application Publication 20240065550</p>	<p>Abstract: This invention is a method or system which uses machine learning and/or artificial intelligence (AI) to adjust, manage, and/or</p>

<p>(pending) "Method or System Using Machine Learning and/or Artificial Intelligence (AI) to Control the Operation of an Implanted Medical Device Based on Biometric Indicators*" filed on 2023-11-03</p>	<p>control the operation of one or more implanted medical devices. This method or system identifies the lagged effects of operating parameters of the one or more implanted medical devices on a person's biometric indicators and then adjusts the operating parameters of the one or more implanted medical devices to change the values of the biometric indicators in a desired direction and/or by a desired amount.</p>
<p>U.S. Patent Application Publication 20190030230 (abandoned) "Wearable and Implanted Closed Loop System for Human Circulatory Assistance" filed on 2018-10-03</p>	<p>Abstract: This invention is a closed-loop system for human circulatory assistance comprising one or more wearable devices which collect data on a biometric parameter concerning a person's body in real time and one or more implanted circulatory assistance devices whose operation is adjusted in real time based on analysis of the data on the biometric parameter. This system can selectively improve blood circulation, either overall or to selected body regions, in order to prevent tissue degradation, promote wound healing, and maintain proper organ functioning.</p>
<p>U.S. Patent Application Publication 20170135633 (abandoned) "Integrated System for Managing Cardiac Rhythm Including Wearable and Implanted Devices*" filed on 2017-01-27</p>	<p>Abstract: This invention is an integrated system for managing cardiac rhythm comprising a wearable device (such as a finger wring or wrist band) that measures body oxygen levels and an implanted cardiac rhythm management device (such as a pacemaker). Working together in an integrated system, a wearable device for measuring oxygen level in body extremities and an implanted device for cardiac rhythm management can help to prevent oxygen deficiencies in body extremities.</p>
<p>U.S. Patent Application Publication 20160045654 (abandoned) "Implanted Extracardiac Device for Circulatory Assistance" filed on 2014-08-14</p>	<p>Abstract: This invention is an implanted extracardiac device for supplementing blood circulation which comprises an implanted blood flow lumen, a blood flow increasing mechanism, and a control unit. Its design improves blood circulation when the blood flow increasing mechanism is operating, without hindering native blood flow when the mechanism is not operating. This device improves circulation without intruding on cardiac tissue or weakening the heart by completely supplanting cardiac function. Also, since the device allows native blood flow when the blood flow increasing mechanism is not in operation, it requires less power and can enable more patient mobility.</p>
<p>U.S. Patent Application Publication 62857942 (expired) "Peripheral Feedback System for Cardiac Rhythm Management with Photoplethysmography (PPG) Device and Implanted Cardiac Pacemaker*" filed on 2019-06-06</p>	<p>In an example, a system for cardiac rhythm management can comprise an implanted cardiac pacemaker whose operation is automatically adjusted based on one or more biometric parameters which are measured by a wearable photoplethysmography (PPG) device. In an example, a peripheral feedback system with both a wearable PPG device and an implanted cardiac pacemaker can help to treat congestive heart failure. In an example, a peripheral feedback system with both a wearable PPG device and a implanted cardiac pacemaker can be used to help diagnosis and/or treat a condition selected from the group consisting of arrhythmia, arteriosclerosis, atherosclerosis, atherosclerotic pathology, fibrillation, autonomic dysfunction, cardio-pulmonary health, congestive heart failure, endothelial dysfunction, hypovolemia, peripheral arterial disease, poor peripheral circulation, premature ventricular contraction, stress level, and tachycardia.</p>

<p>U.S. Provisional Patent Application 62297827 (expired) "System for Automatic Adjustment of Cardiac Function Based on Data from a Wearable Biometric Sensor" filed on 2016-02-20</p>	<p>In an example, this invention can be embodied in a system (or device) for automatic adjustment of an implanted cardiac management device comprising: a wearable component which is configured to be worn on a person's body or clothing; a biometric sensor which is configured to be held in proximity to the surface of the person's body by the wearable component; a data processor which receives data from the biometric sensor; and an implanted cardiac management device which is configured to manage (or control or change) the person's cardiac function, wherein the operation of the implanted cardiac management device is automatically adjusted based on analysis of data from the biometric sensor. In an example, being in proximity to the surface of the person's body can be defined as having at least one part which is worn less than three inches away from the person's body.</p>
<p>U.S. Provisional Patent Application 61866583 (expired) "Stent for Actively Accelerating Blood Flow" filed on 2013-08-16</p>	<p>This invention can be embodied in a device for accelerating blood flow comprising: a stent that is inserted and expanded within a blood vessel; a blood flow accelerating mechanism; a first blood flow lumen formed by the interior of the stent, through which blood passively flows; and a second blood flow lumen wherein blood flow through the second blood flow stream is accelerated by the blood flow accelerating mechanism. This combination of active and passive blood flow can provide relatively minimally-invasive and selectively-adjustable supplemental circulatory assistance for a person for Congestive Heart Failure (CHF). In an example, more than one such device can be implanted into blood vessels to create an extra-cardiac distributed pumping network to supplement the pumping action of the heart and thus lessen heart deterioration.</p>

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