CLAIMS

We ~~disclose and~~ claim:

~~1. A method comprising:~~

~~sensing blood pressure in a sensor disposed on one or both arms of a patient;~~

~~communicating the sensed blood pressure to a pacemaker or implantable cardiac device using a low energy Bluetooth signal;~~

~~sensing thoracic electrical bioimpedance **(TEB);** and~~

~~using the sensed thoracic electrical bioimpedance **(TEB)** together with sensed blood pressure as inputs to the pacemaker or implantable cardiac device in a real-time closed-loop system programmed with a PressurePace algorithm in the pacemaker or implantable cardiac device to treat drug resistant hypertension **(DRH)** or diastolic heart failure including **HFpEF** in the patient,~~

~~wherein the PressurePace algorithm uses machine learning/AI utilizing a continually updated trending analysis of the inputs.~~

~~2. The method of claim 1 further comprising sensing all factors, including blood pressure, resulting in a determination of systemic vascular resistance **(SVR)** as a monitored parameter for control of treatment.~~

~~3. The method of claim 2 using TEB for diagnosis and treatment includes making decision based on determinations of autonomous functioning of the inputs.~~

~~4. The method of claim 1 where sensing thoracic electrical bioimpedance (TEB) is performed in a bioimpedance measurement device integrated into the pacemaker or implantable cardiac device, where the bioimpedance measurement device~~

is all or partly outside the patient's body and where an electrode array communicated to the bioimpedance device is worn externally by the patient.

5. The method of claim 1 where using the sensed thoracic electrical bioimpedance (TEB) is used by the PressurePace algorithm to estimate cardiac output (CO) which in turn is used to estimate systemic vascular resistance (SVR) to calculate right atrial pressure (RAP) or and the estimate systemic vascular resistance (SVR) and sensed blood pressure (systolic blood pressure (SBP), diastolic blood pressure (DBP), or mean arterial pressure (MAP)) is used to calculate right atrial pressure (RAP).

6. The method of claim 1 where using the sensed thoracic electrical bioimpedance (TEB) together with sensed blood pressure as inputs to the pacemaker or implantable cardiac device in a real-time closed-loop system programmed with a PressurePace algorithm in the pacemaker or implantable cardiac device to treat drug resistant hypertension **(DRH)** or diastolic heart failure including **HFpEF** in the patient is not applied to a patient with severe lung disease in order to keep right atrial (RA) pressure constant in the patient as an indirect measure of systemic vascular resistance **(SVR).**

7. The method of claim 1 where the direction of change in systemic vascular resistance **(SVR)** for each increment of time is measured, rather than an absolute value of systemic vascular resistance **(SVR)** as a parameter controlling diagnosis or treatment.

8. The method of claim 1 where the PressurePace algorithm uses machine learning/AI utilizing a continually updated trending analysis of the inputs to calculate a trend in systemic vascular resistance **(SVR),** and

where the PressurePace algorithm detects an increased thoracic bioimpedance **(TEB)** over a matter of hours or days,

where the PressurePace algorithm signals a possible development of increased lung water,

where patterns of changes in systemic vascular resistance **(SVR)** due to pacing and blood pressure dynamics different than the slow onset of heart failure, absent a cardiac catastrophic event, are used to teach using AI the PressurePace algorithm the difference between patterns of changes in systemic vascular resistance **(SVR)** due to pacing and blood pressure dynamics and the slow onset of heart failure,

where the PressurePace algorithm monitors and detects the difference from moment to moment between patterns of changes in systemic vascular resistance **(SVR)** due to pacing and blood pressure dynamics and the slow onset of heart failure, and

whereby **TEB** is used with the PressurePace algorithm and AI to analyze trending of systemic vascular resistance **(SVR)** to detect the occurrence of increased lung water or heart failure.

9. The method of claim 1 where the PressurePace algorithm and machine learning are arranged and configured to detect a difference between thoracic electrical bioimpedance **(TEB)** arising from heart failure **(HF)** and thoracic bioimpedance **(TEB)** arising from increased lung water.

10. The method of claim 5 where estimating cardiac output (CO) using thoracic electrical bioimpedance **(TEB)** to calibrate or regulate heart failure pacemaker or implantable cardiac devices (CRT-Os) that utilize a third left ventricle pacemaker or implantable cardiac device lead.

11. The method of claim 1 further comprising controlling rate modulation of the pacemaker or implantable cardiac device.

12. The method of claim 1 where sensing blood pressure in a sensor disposed on one or both arms of a patient; communicating the sensed blood pressure to a pacemaker or implantable cardiac device using a low energy Bluetooth signal; sensing thoracic electrical bioimpedance **(TEB);** and using the sensed thoracic electrical bioimpedance **(TEB)** together with sensed blood pressure as inputs to the pacemaker or implantable cardiac device in a real-time closed-loop system programmed with a PressurePace algorithm in the pacemaker or implantable cardiac device to treat drug resistant hypertension **(DRH)** or diastolic hemi failure including **HFpEF** in the patient, wherein the PressurePace algorithm uses machine learning/AI utilizing a continually updated trending analysis of the inputs is performed continuously at all times.

13. The method of claim 1 further comprising including subjective patient input into the pacemaker or implantable cardiac device in the real-time closed-loop system programmed with the PressurePace algorithm in the pacemaker or implantable cardiac device to treat drug resistant hypertension **(DRH)** or diastolic heart failure including **HFpEF** in the patient.

14. The improvement of claim 11 where controlling rate modulation of the pacemaker or implantable cardiac device comprises using the PressurePace algorithm to treat hypertension in patients with pacemaker or implantable cardiac devices with no other physiologic sensors supplying inputs, except for:

rate modulation sensors resident in the pacemaker or implantable cardiac device, wherein the sensor inputs for pacemaker or implantable cardiac device rate modulation include heart rate (HR); respiratory rate, a motion sensor, and right atrial (RA) pacing rate; and

rate modulation sensors resident in a blood pressure smart watch including blood pressure and arm position of the smart watch indicating above thorax level, at thorax

level or below thorax level.

15. A blood pressure measuring device comprising: a blood pressure smart watch or ring;

a position sensor included in the watch;

a PressurePace algorithm stored in the smart watch; and

means for allowing the patient to report an adverse event, such as an initiated change in heart rate that has resulted in an adverse symptom, which is used to suspend treatment, resume baseline settings prior to therapy initiation, and continue monitoring,

where the blood pressure smart watch includes an audible and/or flashing indicator that alerts the patient as directed by the PressurePace algorithm.

16. The blood pressure measuring device of claim 15 where calibration of the smart watch is performed using a self-contained module with a USB connection that mates with the smart watch, where module includes an **LED** oximeter simulator driven with a known frequency and powered by a battery, a use indicator that prevents the use of the simulator more than predetermined number of times during a calibration interval, and a timing circuit that strobes the **LED** oximeter simulator to simulate two known blood pressure readings which are input into the watch, namely a high and a low pressure.

17. The blood pressure measuring device of claim 15 in combination with an accelerometer where smart watch is calibrated based on a dynamic measurement of position of the arm as measured by the accelerometer, where the watch measures blood pressure in a variety of positions and where the measured value of blood pressure is stored in each arm position, where data sampling is repeatedly performed during a predetermined number of days before therapy begins to create a database for the monitored patient, where the data is stored and analyzed to establish a mean, standard deviation (SD), other statistical

measures of variability of blood pressure as a function of arm position as measured by the accelerometer included in the smart watch, where after a period of data sampling, a baseline primary measurement variability of the blood pressure measurements of the smart watch in response to different body positions, and where the separate datasets taken over the sampling period are compared to determine what makes them significantly different from each other and therefore reliably distinguishable, where measurements are made during the sampling period to determine real-life primary measurements which are characterized by the percentage contribution of each measurement to a master mean value that is a composite of all three basic arm positions.

18. A method for measurement blood pressure and therapy under a PressurePace algorithm comprising:

updating initial parameters in the PressurePace algorithm;

calculating a first order value of a right atrial pacing rate in a pacemaker or implantable cardiac device;

making a micro-change of right atrial pacing rate during a corresponding micro-interval of time;

then determining if the right atrial pacing rate changed by 1 beat/minute or more, if not returning to making a micro-change of right atrial pacing rate during a corresponding micro-interval of time, otherwise sensing blood pressure and waiting a predetermined period of time, until blood pressure is stable;

analyzing blood pressure data with artificial intelligence to determine if the blood pressure data is consistent with prior blood pressure data corresponding to the patient and time of day;

determining a confidence level of the analysis of the blood pressure data, and the confidence level is insufficient returning to sensing blood pressure and waiting a predetermined period of time, until blood pressure is stable, otherwise determining if a decrease in sensed blood pressure is acceptable;

if the sensed blood pressure is acceptable, then waiting a predetermined period of time without changing right atrial pacing rate and continuing to determine if the right atrial pacing rate changed by 1 beat/minute or more;

if the sensed blood pressure is not acceptable, increasing right atrial pacing rate;

then determining if blood pressure has increased;

if blood pressure has increased, then stopping rate modulation therapy, waiting a predetermined period of time and then calculating a first order value of a right atrial pacing rate; and

if blood pressure has not increased, then determining if a decrease in sensed blood pressure is acceptable.

19. A method for measurement blood pressure and therapy of a patient using a PressurePace algorithm with rate modulation of a pacemaker or implantable cardiac device comprising:

inputting into the PressurePace algorithm a maximum and minimum exercise blood pressure value;

determining if the patient is currently undergoing treatment under the control of the PressurePace algorithm or an thoracic electrical bioimpedance control of the pacemaker or implantable cardiac device;

if the patient is currently undergoing treatment under the control of the PressurePace algorithm or an thoracic electrical bioimpedance control of the pacemaker or implantable cardiac device, then initiating rate modulation of the pacemaker or implantable cardiac device , otherwise sensing blood pressure and determining if the blood pressure value exceeds the input maximum and serially falls;

if the blood pressure value exceeds the input maximum and serially falls, suspending rate modulation treatment and generating an alarm;

otherwise determining if treatment under the control of the PressurePace algorithm or an thoracic electrical bioimpedance control of the pacemaker or implantable

cardiac device decreases heart rate;

if treatment under the control of the PressurePace algorithm or an thoracic electrical bioimpedance control of the pacemaker or implantable cardiac device decreases heart rate, then continuing right atrial pacing with rate modulation under the control of the PressurePace algorithm or an thoracic electrical bioimpedance control of the pacemaker or implantable cardiac device; and

if treatment under the control of the PressurePace algorithm or an thoracic electrical bioimpedance control of the pacemaker or implantable cardiac device does not decrease heart rate, then return to determining if the patient is currently undergoing treatment under the control of the PressurePace algorithm or an thoracic electrical bioimpedance control of the pacemaker or implantable cardiac device.

20. A method for measurement blood pressure and therapy under a PressurePace algorithm with AI and thoracic electrical bioimpedance **(TEB)** using systemic vascular resistance (SVR) comprising:

inputting a maximum and minimum heart rate into the PressurePace algorithm;

sensing changes in blood pressure and systemic vascular resistance **(SVR);**

evaluating sensed changes in blood pressure and systemic vascular resistance **(SVR);**

assigning a category of sensed changes in blood pressure and systemic vascular resistance **(SVR),** including beneficial, possibly beneficial, null, possibly adverse and adverse;

if the assigned the possibly adverse or adverse category, initiating right atrial pacing treatment with the PressurePace algorithm with AI and thoracic electrical bioimpedance (TEB);

making micro-changes in right atrial pacing during corresponding periods of micro-interval times and then waiting a predetermined time period;

sensing blood pressure and systemic vascular resistance **(SVR);**

analyzing sensed blood pressure and systemic vascular resistance **(SVR)** under control by the PressurePace algorithm with AI for consistency with prior sensed blood pressure and systemic vascular resistance (SVR) for the patient and time of day;

determining a confidence level in the treatment under control by the PressurePace algorithm with AI;

if the confidence level is sufficient, then determining whether the treatment under control by the PressurePace algorithm is characterized by an acceptable blood pressure decrease with systemic vascular resistance (SVR) unchanged;

if the confidence level is not sufficient, then returning to sensing blood pressure and systemic vascular resistance (SVR);

if the treatment under control by the PressurePace algorithm is characterized by an acceptable blood pressure decrease with systemic vascular resistance **(SVR)** unchanged, then waiting a predetermined period of time without changing right atrial pacing rate;

determining whether the treatment under control by the PressurePace algorithm is possibly beneficial;

if the treatment under control by the PressurePace algorithm is possibly beneficial, then returning to sensing blood pressure and systemic vascular resistance **(SVR);**

if the treatment under control by the PressurePace algorithm is not characterized by an acceptable blood pressure decrease with systemic vascular resistance **(SVR)** unchanged, then determining whether the sensed blood pressure was constant and the and systemic vascular resistance **(SVR)** fell;

if the sensed blood pressure was constant and the and systemic vascular resistance **(SVR)** fell, then forebear from increasing the right atrial pacing rate and wait a predetermined period of time, after which return to sensing blood pressure and systemic vascular resistance **(SVR);**

if the sensed blood pressure was not constant and the and systemic vascular resistance **(SVR)** did not fall, then determine if the sensed blood pressure and systemic

vascular resistance **(SVR)** fell and are acceptable;

if the sensed blood pressure and systemic vascular resistance **(SVR)** fell and are acceptable, then return to making micro-changes in right atrial pacing during corresponding periods of micro-interval times and then waiting a predetermined time period;

if the sensed blood pressure and systemic vascular resistance **(SVR)** did not fall and are not acceptable, then determine if the sensed blood pressure and systemic vascular resistance **(SVR)** remained constant;

if the sensed blood pressure and systemic vascular resistance **(SVR)** remained constant, then increase the right atrial pacing rate and wait a predetermined period of time and return to making micro-changes in right atrial pacing during corresponding periods of micro-interval times and then waiting a predetermined time period;

if the sensed blood pressure and systemic vascular resistance **(SVR)** changed, then determine if the sensed blood pressure and systemic vascular resistance **(SVR)** are adverse or possibly adverse;

if the sensed blood pressure and systemic vascular resistance **(SVR)** are adverse or possibly adverse, then suspend treatment by the PressurePace algorithm and monitor the sensed blood pressure and systemic vascular resistance **(SVR);**

if the sensed blood pressure and systemic vascular resistance **(SVR)** are not adverse or not possibly adverse, then return to sensing blood pressure and systemic vascular resistance **(SVR);**

if treatment by the PressurePace algorithm is suspended, then determine whether the sensed blood pressure and systemic vascular resistance **(SVR)** are within a predetermined range;

if the sensed blood pressure and systemic vascular resistance **(SVR)** are not within a predetermined range, then continue to suspend treatment by the PressurePace algorithm and monitor the sensed blood pressure and systemic vascular resistance **(SVR);** and

if the sensed blood pressure and systemic vascular resistance **(SVR)** are

within a predetermined range, then wait a predetermined period of time and then return to making micro-changes in right atrial pacing during corresponding periods of micro- interval times and then waiting a predetermined time period.

22. A method for measurement blood pressure and therapy under a PressurePace algorithm with a calibrated or corrected watch for a patient comprising:

inputting a treatment goal in the PressurePace algorithm;

sensing blood pressure;

establishing a baseline reading and variability of sensed blood pressure data, time of day and arm position of the watch for the patient;

determining whether sensed blood pressure is consistent with the established baseline reading and variability of sensed blood pressure data, time of day and arm position of the watch for the patient;

if the sensed blood pressure is not consistent with the established baseline reading and variability of sensed blood pressure data, time of day and arm position of the watch for the patient, then return to establishing a baseline reading and variability of sensed blood pressure data, time of day and arm position of the watch for the patient;

if the sensed blood pressure is consistent with the established baseline reading and variability of sensed blood pressure data, time of day and arm position of the watch for the patient, then make micro-changes in a right atrial pacing rate in corresponding micro-intervals of time and wait a predetermined period of time;

then sensing blood pressure data;

analyzing blood data with artificial intelligence for consistency with prior blood pressure data for the patient and time of day;

determining a confidence level in the for consistency with prior blood pressure data for the patient and time of day;

if the confidence level is insufficient, then return to sensing blood pressure data;

if the confidence level is sufficient, then determine if treatment under the control

of the PressurePace algorithm leads to an acceptable decrease in blood pressure;

if treatment under the control of the PressurePace algorithm leads to an acceptable decrease in blood pressure, then wait a predetermined period of time, maintain right atrial pacing at a constant rate and return to making micro-changes in the right atrial pacing rate in corresponding micro-intervals of time and waiting a predetermined period of time;

if treatment under the control of the PressurePace algorithm does not lead to an acceptable decrease in blood pressure, then determine if there is no change in blood pressure;

if there is no change in blood pressure, then wait a predetermined period of time and return to making micro-changes in the right atrial pacing rate in corresponding micro-intervals of time and waiting a predetermined period of time;

if there is a change in blood pressure, then determine if the blood pressure increased;

if the blood pressure has not increased, return to making micro-changes in the right atrial pacing rate in corresponding micro-intervals of time and waiting a predetermined period of time;

if the blood pressure increased, wait for a predetermined period of time and redetermine if the blood pressure increased;

if after waiting for a predetermined period of time, the sensed blood pressure has still increased, suspend treatment by the PressurePace algorithm; and

if after waiting for a predetermined period of time, the sensed blood pressure has not increased, return to making micro-changes in the right atrial pacing rate in corresponding micro-intervals of time and waiting a predetermined period of time;

23. A pacing system with inputs of real-time variables, including physiologic data from a sensor platform, blood pressure, physiologic parameters from a pacemaker or implantable cardiac device , including heart rate (HR), accelerometer data,

~~respiratory rate, and thoracic electrical bioimpedance data, and patient-derived subjective data comprising:~~

~~a machine learning module receiving the real-time variables, including physiologic data from a sensor platform, blood pressure, physiologic parameters from a pacemaker or implantable cardiac device, including heart rate (HR), accelerometer data, respiratory rate, and thoracic electrical bioimpedance data, and patient-derived subjective data,~~

~~where the machine learning module recognizes a dataset to achieve a predetermined optimum blood pressure result and a predetermined set of physiologic parameters, including the patient's best sense of wellbeing to calculate a target parameter dataset for treatment; and~~

~~means to autonomously initiate treatment according to a micro-trend analysis, then to observe the results for each micro-interval of time, to make adjustments, to learn, and to treat again, or to suspend treatment and to loop back and repeat treatment using a micro-trend analysis, then to observe the results for each micro-interval of time, to make adjustments, to learn, and to treat again, or to suspend treatment.~~

1. A computing device, comprising at least one processor and at least one memory comprising instructions that, when executed by the at least one processor, cause the computing device to perform operations comprising:

receiving a first blood pressure value and a subsequent second blood pressure value;

receiving a first systemic vascular resistance (SVR) value and a subsequent second SVR value;

determining a change in blood pressure based on the first blood pressure value and the second blood pressure value;

determining a change in SVR based on the first SVR value and the second SVR value;

determining a pacing rate based on the change in blood pressure and the change in SVR;

providing a first initial micro-interval pacing rate based on the pacing rate;

receiving a third blood pressure value and a third SVR value in response to providing the first initial micro-interval pacing rate;

providing the third blood pressure value and third SVR to an artificial intelligence module trained to output a patient blood pressure category, wherein the artificial intelligence module is trained based on historical patient blood pressure data;

receiving an artificial intelligence module output from the artificial intelligence module, the artificial intelligence module output comprising a patient blood pressure category; and

determining a pacing action based on the patient blood pressure category.

2. The computing device of claim 1, wherein determining the pacing rate is in response to identifying an adverse event based on the change in blood pressure and the change in SVR.

3. The computing device of claim 2, wherein identifying the adverse event comprises one of:

identifying a drop in blood pressure based on the change in blood pressure and identifying a rise in SVR based on the change in SVR;

identifying an increase in blood pressure based on the change in blood pressure and identifying the rise in SVR;

identifying a drop in blood pressure below a minimum blood pressure and identifying a stable SVR based on the change in SVR; or

identifying the increase in blood pressure and identifying the stable SVR.

4. The computing device of any of claims 1-3, wherein a micro-interval of the first initial micro-interval pacing rate is a fraction of the pacing rate.

5. The computing device of any of claims 1-4, wherein the patient blood pressure category is selected from one of a decrease in blood pressure by a successful amount, a decrease in blood pressure by an unacceptable amount, or a stable blood pressure.

6. The computing device of claim 5, wherein the determining the pacing action based on the patient blood pressure category being the decrease in blood pressure by a successful amount comprises:

receiving a third SVR; and

determining the pacing action is one of suspending the operations based on the third SVR meeting a target SVR, providing a second initial micro-interval pacing rate based on the third SVR not meeting the target SVR.

7. The computing device any of claims 5-6, wherein the pacing action based on the patient blood pressure category being the decrease in blood pressure by an unacceptable amount comprises suspending the operations.

8. The computing device of any of claims 5-7, wherein determining the pacing action based on the patient blood pressure category being the stable blood pressure comprises:

receiving a third SVR; and

determining the pacing action is providing an updated micro-interval pacing rate based on the third SVR indicating a stable SVR.

9. The computing device of claim 8, wherein the updated micro-interval pacing rate is greater than the first initial micro-interval pacing rate.

10. A method for cardiac pacing, the method comprising:

receiving a first blood pressure value and a subsequent second blood pressure value;

receiving a first systemic vascular resistance (SVR) value and a subsequent second SVR value;

determining a change in blood pressure based on the first blood pressure value and the second blood pressure value;

determining a change in SVR based on the first SVR value and the second SVR value;

determining a pacing rate based on the change in blood pressure and the change in SVR;

providing a first initial micro-interval pacing rate based on the pacing rate;

receiving a third blood pressure value and a third SVR value in response to providing the first initial micro-interval pacing rate;

providing the third blood pressure value and third SVR to an artificial intelligence module trained to output a patient blood pressure category, wherein the artificial intelligence module is trained based on historical patient blood pressure data;

receiving an artificial intelligence module output from the artificial intelligence module, the artificial intelligence module output comprising a patient blood pressure category; and

determining a pacing action based on the patient blood pressure category.

11. The method of claim 10, wherein the patient blood pressure category is selected from one of a decrease in blood pressure by a successful amount, a decrease in blood pressure by an unacceptable amount, or a stable blood pressure.

12. The method of any of claims 10-11, wherein the determining the pacing action based on the patient blood pressure category being the decrease in blood pressure by a successful amount comprises:

receiving a third SVR; and

determining the pacing action is one of suspending the cardiac pacing based on the third SVR meeting a target SVR, providing a second initial micro-interval pacing rate based on the third SVR not meeting the target SVR.

13. The method of any of claims 10-12, wherein the pacing action based on the patient blood pressure category being the decrease in blood pressure by an unacceptable amount comprises deactivating the cardiac pacing.

14. The method of any of claims 10-13, wherein determining the pacing action based on the patient blood pressure category being the stable blood pressure comprises:

receiving a third SVR; and

determining the pacing action is providing an updated micro-interval pacing rate based on the third SVR indicating a stable SVR.

15. A method for cardiac pacing, the method comprising:

receiving a blood pressure baseline for treatment (BAT);

receiving a blood pressure treatment goal;

determining a pacing rate based on the blood pressure BAT and blood pressure treatment goal;

providing a initial micro-interval pacing rate based on the pacing rate;

receiving a detected blood pressure value in response to providing the initial micro-interval pacing rate;

determining that the detected blood pressure value is a confident detected value based on an output of an artificial intelligence model, the artificial intelligence model being trained based on the blood pressure BAT;

determining that the detected blood pressure value is an unacceptable blood pressure value in response to determining that detected blood pressure value is the confident detected value; and

providing an updated micro-interval pacing rate based on the pacing rate, the updated micro-interval pacing rate being greater than the initial micro-interval pacing rate.

16. The method of claim 15, wherein the initial micro-interval pacing rate is a first fraction of the pacing rate and the updated micro-interval pacing rate is a second fraction of the pacing rate, the first fraction being smaller than the second fraction.

17. The method of any of claims 15-16, wherein the blood pressure BAT comprises time of day based blood pressure values and wherein determining that the detected blood pressure

value is a confident detected value comprises:

receiving, by the artificial intelligence model, a time of day;

comparing, by the artificial intelligence model, the detected blood pressure value to a time of day specific blood pressure BAT value; and

generating the output of the artificial intelligence model based on comparing the detected blood pressure value to the time of day specific blood pressure BAT value.