

WHAT IS CLAIMED IS:

WE CLAIM:

1. A method of detecting an impending cardiac decompensation of a patient, the method comprising:

measuring at least two of an electrocardiogram signal of the patient, a hydration signal of the patient, a respiration signal of the patient or an activity signal of the patient; and

combining the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal to detect the impending cardiac decompensation.

2. The method of claim 1 wherein the at least two comprise at least three of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal and the at least three are measured and combined to detect the impending cardiac decompensation.

3. The method of claim 2 wherein the at least three comprise at least four of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal and the at least four are measured and combined to detect the impending cardiac decompensation.

4. The method of claim 1 wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal are used simultaneously to determine impending cardiac decompensation.

5. The method of claim 1 wherein combining comprises using the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal to look up a value in a previously existing array.

6. The method of claim 1 wherein combining comprises at least one of adding, subtracting, multiplying, scaling or dividing the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal.

7. The method of claim 1 wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal are combined with at least one of a weighted combination, a tiered combination or a logic gated combination, a time weighted combination or a rate of change.

~~8. The method of claim 1 wherein a flag status is determined in response to the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal.~~

~~9. The method of claim 8 wherein the flag status is determined in response to a change in the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal.~~

~~10. The method of claim 8 wherein additional signal measurements of the patient are made in response to the flag status.~~

~~11. The method of claim 1 wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal are combined in response to a time of day.~~

~~12. The method of claim 1 wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal comprise at least one of a derived signal, a time averaged signal, a filtered signal or a raw signal.~~

~~13. The method of claim 1 further comprising determining baseline values of the patient for the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal and wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal signals comprise changes from the baseline values.~~

~~14. The method of claim 1 wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal comprise differences from baseline values of a patient population and wherein the impending decompensation is detected in response to the differences from the baseline value of the patient population.~~

~~15. The method of claim 1 wherein the hydration signal comprises an impedance signal and the activity signal comprise an accelerometer signal.~~

~~16. The method of claim 1 wherein the activity signal comprise an accelerometer signal to determine a posture of the patient.~~

~~17. The method of claim 16 wherein the accelerometer signal comprises a three dimensional inclination signal to determine a three dimensional orientation of the patient.~~

~~18. The method of claim 1 wherein a temperature signal is combined with the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal to detect the impending cardiac decompensation.~~

~~19. The method of claim 1 further comprising transmitting the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal to a remote site where the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal are combined to detect the impending cardiac decompensation.~~

~~20. The method of claim 1 further comprising transmitting instructions from a remote site to a processor supported with the patient, and wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal are combined with the processor in response to the instructions to detect the impending cardiac decompensation.~~

21. A system to detect impending cardiac decompensation of a patient, the system comprising:
circuitry (130, 134, 136, 138, 152) to measure ~~at least two of an electrocardiogram signal of the patient, a hydration signal of an impedance associated with the patient, or an activity signal~~ and a temperature of a skin of the patient; and

a processor system (100, 102, 106, or 146) comprising a tangible medium in communication with the circuitry (130, 134, 136, 138, 152), the processor system (100, 102, 106, or 146) configured to ~~combine the at least two of the electrocardiogram signal, calculate a hydration measurement based on the measured impedance and corrects the calculated hydration measurements based on the measured skin temperature of the patient,~~ wherein the processor system utilizes the corrected hydration signal, the respiration signal or the activity signal measurement to detect the impending cardiac decompensation of the patient.

Commented [M1]: The Examiner, in FER under “NON-PATENTABILITY” has objected that the claims fall under section 3(i) of The Patents Act. As per Indian Patent law, claims relating to “any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.” fall under Sections 3(i) are considered as non-patentable subject matter. Therefore, to overcome this objection, we have cancelled method claims 1-20.

Commented [M2]: Support can be found at least in paragraph [0064]

~~222.~~ The system ~~of claim 21 as claimed in claim 1,~~ wherein the processor system (100, 102, 106, or 146) comprises a least one processor a location remote from the patient configured to detect the decompensation.

~~233.~~ The system ~~of claim 21 as claimed in claim 1,~~ wherein the processor system (100, 102, 106, or 146), supported with the patient, receives instructions transmitted from a remote site and ~~combines the at least two~~ calculates the hydration measurement in response to the instructions to detect the impending cardiac decompensation.

~~244.~~ The system ~~of claim 21 as claimed in claim 1,~~ wherein the ~~at least two~~ comprise at least three of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal and the at least three are measured and combined circuitry (130, 134, 136, 138, 152) measures one or more of an electrocardiogram signal of the patient, a respiration signal, and an activity signal and combines the one or more measured signals with the corrected hydration measurement to detect the impending cardiac decompensation.

~~255.~~ The system ~~of claim 24 as claimed in claim 4,~~ wherein ~~the at least three~~ comprise at least four two or more of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal ~~and the at least four~~ are measured and combined with the corrected hydration measurement to detect the impending cardiac decompensation.

~~266.~~ The system ~~of claim 21 as claimed in claim 4,~~ wherein the processor system (100, 102, 106, or 146) simultaneously uses the ~~at least two~~ one or more ~~-of~~ of the electrocardiogram signal, ~~the hydration signal,~~ the respiration signal or the activity signal in combination with the corrected hydration measurement to determine impending cardiac decompensation.

~~27.~~ The system ~~of claim 21 wherein combining~~ ~~comprises the processor system using the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal to look up a value in a previously existing array.~~

~~28.~~ The system ~~of claim 21 wherein combining~~ ~~comprises at least one of adding, subtracting, multiplying, scaling or dividing the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal.~~

~~29. The system of claim 21 wherein the processor system combines the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal with at least one of a weighted combination, a tiered combination or a logic gated combination, a time weighted combination or a rate of change.~~

~~30. The system of claim 21 wherein the processor system determines a flag status in response to the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal.~~

~~31. The system of claim 28 wherein the processor system determines the flag status in response to a change in the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal.~~

~~32. The system of claim 28 wherein the processor system affects the circuitry to make additional signal measurements of the patient in response to the flag status.~~

~~33. The system of claim 21 as claimed in claim 4, wherein the processor system (100, 102, 106, or 146) combines the at least two one or more of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal with the corrected hydration measurement in response to a time of day.~~

~~34. The system of claim 21 wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal comprise at least one of a derived signal, a time averaged signal, a filtered signal or a raw signal.~~

~~35. The system of claim 21 wherein the processor determines baseline values of the patient for the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal and wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal signals comprise changes from the baseline values.~~

~~36. The system of claim 21 wherein the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal comprise differences from baseline~~

~~values of a patient population and wherein the impending decompensation is detected in response to the differences from the baseline value of the patient population.~~

~~37. The system of claim 21 wherein the hydration signal comprises an impedance signal and the activity signal comprise an accelerometer signal.~~

~~38. The system of claim 21 as claimed in claim 4, wherein the activity signal comprises an accelerometer signal to determine a posture of the patient.~~

~~39. The system of claim 36 as claimed in claim 8, wherein the accelerometer signal comprises a three dimensional inclination signal to determine a three dimensional orientation of the patient.~~

~~40. The system of claim 21 wherein the processor system combines a temperature signal with the at least two of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal to detect the impending cardiac decompensation.~~

~~41. The system of claim 21 as claimed in claim 4, wherein the processor transmits the at least two one or more of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal to a remote site where the at least two one or more of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal are combined with the corrected hydration signal to detect the impending cardiac decompensation.~~

~~42. The system of claim 21 as claimed in claim 4, further comprising transmitting instructions from a remote site to a processor supported with the patient, and wherein the processor combines at least two the one or more of the electrocardiogram signal, the hydration signal, the respiration signal or the activity signal with the corrected hydration signal in response to the instructions to detect the impending cardiac decompensation.~~

12. The system as claimed in claim 1, wherein the circuitry (130, 134, 136, 138, 152) places a voltage and/or current at one or more of electrodes connected to the circuitry (130, 134, 136, 138, 152) having a frequency between 0.5 kHz and about 20 kHz such that the hydration measurement corresponds to the extracellular fluid of the patient.

Commented [M3]: Support can be found at least in paragraph [0070]

13. The system as claimed in claim 1, wherein the processor system (100, 102, 106, or 146) corrects the calculated hydration measurement by lowering the hydration measurement in response to an increase in measured skin temperature.

Commented [M4]: Support can be found at least in paragraph [0064]

14. The system as claimed in claim 1, wherein the processor system (100, 102, 106, or 146) corrects the calculated hydration measurement by increasing the hydration measurement in response to a decrease in the measured skin temperature.

Commented [M5]: Support can be found at least in paragraph [0064]

15. The system as claimed in claim 1, wherein the processor system (100, 102, 106, or 146) corrects the calculated hydration measurement such that the hydration measurement remains substantially unchanged when the measured impedance decreases and the skin temperature increases.

Commented [M6]: Support can be found at least in paragraph [0064]