CLAIMS

1. A bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes, comprising:

a device for measuring pain matrix activity comprising a sensor set configured to be placed contralaterally on the body and at least one additional sensor configured to be placed ipsilaterally on the body, the device configured to measure differences in either voltage or current from measurements taken from the contralateral sensors to detect pain matrix response as deflections of the related biosignal indicating an increase or decrease of an individual's experience of pain; and

the device configured to measure differences in either impedance, conductance, voltage or current from measurements from one of the contralateral sensors and from the at least one ipsilateral sensor in order to calibrate and normalize the contralateral sensors' acquired biosignal;

a controller and/or processor configured to collect and derive pain matrix activity data from the contralateral and ipsilateral sensor signals;

a non-transitory computer readable medium within a network of central processing units having memory and data storage and having embodied thereon one or more computer programs causing one or more of the central processing units to execute certain steps of:

accessing the measured pain matrix activity and a plurality of BioTrace Factors related to biophysical, biological, psychological, social, environmental, and demographic information of the individual and of other individuals;

identifying a population having similar BioTrace Factors; and

identifying treatments and treatment outcomes of the individual and the similarly situated population and correlating these treatments and treatment outcomes to the biosignal deflections related to pain matrix activity to determine the effectiveness of the individual's treatment.

2. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 and wherein one or more controllers and/or processors being configured to normalize the

measured pain matrix activity to a scale based on measured pain matrix activity of the similarly situated population to provide a quantitative measure of pain.

3. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 2 wherein the quantitative measure of pain matrix activity correlates with self-reporting of pain using a numerical rating scale.

4. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 and wherein the controller and/or processor being configured to collect data based on 10-60 messaging triggered by threshold-based alerts set from tolerance levels of pain determined from the measured pain matrix activity, BioTrace Factors, integrated journaling and responses to directed information acquisition.

5. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein the controller and/or processor being configured to collect data on contribution factors and factor impact levels.

6. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 comprising a noxious stimulus caliper configured to apply a consistent and repeatable amount of pressure for a consistent period of time; and

wherein the controller and /or processor being configured to normalize an individual patient’s experience to pain comprising a combination of pain matrix activity measurements based on the individual’s monitored response during the standard noxious stimulus and the individual patient’s BioTrace Factors to reflect an individual patient’s normalized response to pain.

7. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 and wherein the controller and/or processor being configured to determine a BioTrace Progress Score reflective of the effectiveness of a patient’s treatment and measurement of a patient’s compliance to that treatment.

8. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein the controller and/or processor being configured to measure pain matrix activity without applying a voltage.

9. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein the controller and/or processor being configured to measure pain matrix activity with applying a voltage.

10. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein at least one of the ipsilateral sensors of the device for measuring pain matrix activity measures impedance to determine differences in each contralateral sensor's contact to the skin to calibrate the contralateral sensor set.

11. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein the controller and/or processor being configured to apply a float current to the sensors intermittently.

12. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein the controller and/or processor being configured to measure conductance using at least one of the sensors of the device for measuring pain matrix activity.

13. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein a voltage is applied to at least one of the sensors of the device for measuring pain matrix activity that are placed ipsilaterally.

14. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein the sensors of the device for measuring pain matrix activity are in pairs placed contralaterally and in pairs placed ipsilaterally.

15. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1

wherein the sensors of the device for measuring pain matrix activity are two pairs of ipsilateral sensors placed contralaterally.

16. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein the device for measuring pain matrix activity comprises a load resistor having resistance of between 0.5k ohms and 900k ohms.

17. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 16 wherein the load resistor is a variable resistor.

18. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 17 wherein the controller and/or processor being configured to incrementally increase resistance and apply voltage to generate a linear resistance curve.

19. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 18 wherein the controller and/or processor being configured to adjust the variable resistor using the linear resistance curve to produce maximum current flow.

20. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 comprising a noxious stimulus caliper that applies a consistent and repeatable amount of pressure for a consistent period of time.

21. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 20 wherein pain matrix activity measurements from the applied stimulus using the noxious stimulus caliper are used to generate a baseline of pain tolerance.

22. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 comprising a motion detector for activity monitoring.

23. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 comprising a heart rate monitor.

24. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 comprising a heart rate variability monitor.

25. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 comprising a blood pressure monitor.

26. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 comprising a galvanic skin response measurement device.

27. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 comprising a skin temperature measurement device.

28. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 wherein the device for measuring pain matrix activity comprises a pain matrix monitoring device, heart rate monitor, heart rate variability monitor, blood pressure monitor, galvanic skin response measurement device, temperature measurement device, and motion detector.

29. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 and wherein the controller and/or processor being configured to operate the bioanalytical analysis system as a SaaS, PaaS and on demand computing services and as a shared resource database through a web browser or other interface.

30. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1 and wherein the controller and/or processor being configured to operate the bioanalytical analysis system to perform the execution of steps for the initialization, identification, location, acquisition, control and communication to the device for measuring pain matrix activity.

31. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 1, comprising:

a flexible sensor attachment device having a track and conductive strip; and

wherein the flexible sensor attachment device provides for the attachment and electrical connection to a plurality of electrodes and sensors.

32. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 31 wherein the flexible sensor attachment is formed as a sensor track comprising the integration of the sensor track to clothing.

33. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 32 comprising an adhesive strip or Velcro hook and loop fastener for the attachment of the sensor track to skin, clothing or other surfaces.

34. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 31 comprising an electronic circuit for the initialization, identification, location, acquisition, control and communication to the plurality of electrodes and sensors.

35. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 31 comprising wireless communication circuitry.

36. The bioanalytical analysis system using a direct pain biosignal measurement to diagnose pain and measure the effectiveness of treatment outcomes of claim 31 comprising communication connectors to add separate sensor tracks and additional electrodes and sensors to the sensor track.