We claim:

1. A system for detecting the presence of a right-to-left pulmonary shunt in a patient, comprising the steps:

providing an indicator delivery system having an outlet located in a vein of the patient in blood flow communication with the right side of the heart and actuateable to define an anticipated transit time substantially from the commencement of delivery of indicator toward the vein and the arrival of such indicator at a pulmonary location such as the right side of the heart;

said indicator delivery system being actuateable to cue the injection of a fluorescing biocompatible dye excitable by tissue penetrating excitation radiation to derive fluorescence emission corresponding with the indicator concentration;

a sensor comprising a photodiode emitter energizable to generate light at the excitation radiation wavelength and a photodetector which is filtered for response substantially only to the fluorescence emission.

providing a transmissive sensor positionable to sense the presence of at least a portion of the indicator at arterial vasculature of one or of symmetrically paired distal locations of the patient and having one or more outputs corresponding with the instantaneous concentration of indicator at such vasculature;

providing a monitor/controller having a display and responsive to said actuation to commence timing the anticipated transit time, responsive to a sensor output to display one or more indicator dilution curves to determine the nature of a circulatory anomaly.

2. The method of claim 1 wherein the paired distal location is one or more ears, the hand, the neck, the leg, and the arm.

3. The method of claim 1 further comprising the steps:

providing a manometer with said monitor/controller having an air pressure responsive input and a corresponding pressure output signal;

providing a pneumatic tube with a mouthpiece engageable with the mouth for receiving the exhalation of a Valsalva Maneuver;

determining an anticipated transit time;

determining the interval of said Valsalva Maneuver; and

configuring the monitor/controller to display the start and cue the release of the determined Vasalva Maneuver and to cue the time of actuation of the indicator delivery system with respect to such start and release.

4. The method of claim 3 further comprising the steps:

providing an electromagnetically operated pneumatic valve at the monitor/controller coupled with the pneumatic tube and actuateable to a vent-to-atmosphere orientation from an open to the venting orientation and actuateable by the monitor/controller in response the cue.

5. The system of claim 3 in which the monitor/controller is responsive to publish the normal indicator/dilution curve and any premature indicator/dilution curves at its display.

6. The system of claim 5 in which the monitor/controller publishes the indicator/dilution curves in the form of a shunt conductance index.

7. The system of claim 1 in which:

the circulatory anomaly is one or more of a cardiac shunt, a patent foramen ovale and a pulmonary-arterial venous malformation.

8. The system of claim 7 in which:

the monitor/controller is responsive to compare the calculated area A_{normal} with a minimum value area A_{min}, and is responsive to generate an audible alarm, error message and prompt when A_{normal} is less than A_{min}.

9. The system of claim 1 in which:

the indicator delivery system includes a flow sensor responsive to derive signals corresponding with the commencement and termination of fluid flow

through the system; and

the monitor/controller is responsive to such commencement and termination signals to derive an audible alarm to the operator when the time interval of indicator injection is excessive.

10. The system of claim 1 in which the indicator delivery system injected fluorescing biocompatible dye is indocyanine green dye.

11. The system of claim 1 in which the sensor further comprises a sensor array with transmission mode sensing in which:

the sensor array comprises two or more paired excitation laser diodes and filtered photodetectors and energizable in a sequence of such pairs or simultaneously; and

the monitor/controller is responsive to elect one or more of that pair exhibiting a concentrator output of highest intensity, a maximum shunt conductance index and an average detection signal.

12. The system of claim 11 in which the sensor array further comprises the laser diodes arranged with an aspheric collimating lens, a collimator plate and an interference filter in the transmission path to the photodetector.

13. The system of claim 11 in which:

the sensor array excitation laser diodes are energizable to emit light at a wavelength of 785 nanometers.

13. The system of claim 2 in which the sensor positionable at paired distal locations further comprises two fluorescence sensing array fixtures with sensing array arms, removeably attached to a headband.

14. The system of claim 13 wherein the paired distal location is at the schaphoid fossa of ears of the patient.

15. The system of claim 14 wherein the apparatus is configured for use on a human patient.

16. The system of claim 1 in which:

the indicator delivery assembly comprises a flexible elongate delivery tube extending between proximal and distal ends, an auxiliary catheter coupled in fluid transfer relationship with the distal end defining the outlet, a indicator fluid flow detector coupled in fluid transfer relationship with the proximal end and deriving signals corresponding with the commencement and termination of fluid flow through the system, a three-way valve connected upstream to the fluid flow sensor, a first indicator containing syringe coupled in indicator flow relationship with the valve and actuateable to cause indicator to flow through the valve, and a second isotonic saline fluid containing syringe coupled in fluid flow relationship with the valve and actuateable to cause isotonic saline to flow through the valve; and

the monitor/controller is responsive to cue the operator first to actuate the first syringe and immediately thereafter to actuate the second syringe, and is responsive to monitor the corresponding fluid flow sensor signals.

17. The system of claim 16 wherein the flexible elongate delivery tube is preloaded with a quantity of indicator from the first indicator containing syringe, the valve is actuated to connect with the second isotonic saline fluid containing syringe, and upon actuation of the second syringe the fluid flow sensor signals as transmitted to the monitor/controller.

18. The system of claim 1 wherein the apparatus of the system is configurable for use with a patient that is a cat, a dog, an elephant, a horse, or a human.

19. A sensing array apparatus comprising

(a) a plurality of laser diode emitter and photodetector pairs for monitoring the fluorescence of a fluorescing circulatory tracking reagent;

b) said laser diode emitters providing a excitation light source emitting a first wavelength for excitation of an indicator within the tissue of a patient

body, the emitters transmitting the excitation light through a collimator lens having a collimating channel aligned with an optical path an interference filter, said collimating channel and interference filter located intermediate to said laser diode emitter and photodetector; and

(c) said detectors for measuring the intensity of the fluorescent light emitted by the tracking reagent at a second wavelength from an excited indicator within the blood stream; and,

(d) a support system of a plurality of array support arms;

wherein the clamping array support system can placed in a clamping arrangement on the exterior of the patient body, whereupon activation of one or more of the laser diode emitters said laser diode emitters transmit excitation light through tissue of the patient, thereby exciting indicator present, said photodetectors measuring the intensity of light emitted by excited indicator.

20. The sensing array apparatus of claim 19 wherein the plurality of laser diode emitter and photodetector pairs are three laser diode emitter and photodetector pairs.

21. The sensing array apparatus of claim 19 wherein two sensing array apparatuses are used at symmetrical locations on the human body.

23. The sensing array apparatus of claim 19 the support system further comprises positionable wedges for positioning the sensing array apparatuses on the ear.

24. The sensing array apparatus of claim 16 further comprising a sensor array with a fixed throat opening.

25. A pulmonary anomaly detection apparatus wherein a biocompatible indicator is provided, said indicator being excitable by energy at a first wavelength to emit fluorescent energy of a second, higher wavelength, such system having a transmission mode sensing device, comprising:

a first branch with an excitation assembly operationally engageable with one surface of an ear scaphoid fossa and having at least one laser energizable to emit photon energy at said first wavelength along one or more optical paths and a one or more corresponding collimating lenses, each disposed within an optical path of a laser directing collimated photon energy at said first wavelength through said one surface; and

a second branch with a sensor assembly corresponding with said excitation assembly operationally engageable with the ear scaphoid fossa at another surface opposite said one surface and having a photodetector aligned with each optical path excitable by impinging photons to derive an intensity signal, an interference filter located between said other surface opposite said one surface and a photodetector and exhibiting a bandpass corresponding with said fluorescent energy at the second higher wavelength.

26. The system of claim 25 wherein said sensor assembly further comprises:

a first collimator having a collimating channel aligned with an optical path and located intermediate the other surface of the ear scaphoid fossa and an interference filter, and a second collimator having a collimating channel aligned with an optical path and located between the interference filter and the photodetector.

27. The system of claim 25 in which:

each said first and second branch respective excitation assembly and sensor assembly comprises respectively, an array of two or more lasers and corresponding two or more photodetectors; and .

said first and second branches are joined together to form a fixed thoat.

28. The system of claim 25 in which:

said first and second branches are cooperatively configured to have an optical interlock formed with a light emitting diode in one branch with a light output along an interlock optical path and a photodetector aligned with the interlink optical path and located in the opposite branch.

29. A kit supplying consumable materials necessary for quantifying a circulatory anomaly comprising:

a) an indicator delivery tubing system providing a valve, syringe connectors, a flow sensor and sterile intravenous injector;

b) one or more doses of circulatory indicator reagent as a shelf stable material;

b) a diluent for preparing the dose of circulatory indicator reagent for injection or for delivering an indicator bolus;

c) a dose of nonreactive blood compatible clearing reagent for completing the injection; and

d) a Valsalva mouthpiece apparatus with a mouthpiece and monitor connector coupling.

30. The kit of claim 29 further comprising a flow sensor that is a single use flow sensor with a circuit that in communication with a monitor-controller that is disabled for repeat use after initiation of a testing procedure.

31. The kit of claim 28 further comprising a sealed tray containing the kit contents in a sterile condition until opened.

We claim:

1. A system for detecting the presence of a right-to-left cardiac shunt in a patient, comprising:

an indicator delivery system having an outlet locatable in a vein of the patient in blood flow communication with the right side of the heart and actuatable to deliver a fluorescing biocompatiable indicator into the vein such that the indicator will arrive at the right side of the heart within an anticipated transit time;

at least one non-invasive optical sensor positionable along a skin surface of the patient to detect the presence of at least a portion of the indicator as it flows through the underlying arterial vasculature and comprising a fixture, a plurality of laser diode emitters located in the fixture along one side of a tissue receiving gap therein and energizable to emit light at a first wavelength that will transcutaneously excite the indicator, and a like number of photodetectors located in the housing along an opposite side of the tissue receiving gap therein for detecting the concentration-indicating intensity of fluorescing photons that will be emitted by the indicator at a second wavelength as a result of excitation light from the emitters being transmitted through the subject tissue and underlying vasculature;

one or more sensor outputs corresponding with the instantaneous concentration of indicator flowing through said vasculature at the sensor location; and

a monitor/controller having a display, the monitor/controller programmed to cue actuation of the indicator delivery system, to commence timing of the anticipated indicator transit time, to display one or more premature and/or normal indicator dilution curves and, when a shunt is detected, to calculate a shunt conductance index by comparing the ratio of the peak amplitude of a premature indicator dilution curve to the peak amplitude of an associated normal indicator dilution curve.

2. The system of claim 1 wherein the at least one sensor is adapted for location at one or more ears, the nose, either or both the top and bottom lip, the hand, one or more fingers, the neck, the leg, one or more toes, or the arm.

3. The system of claim 1 further comprising:

a manometer in communication with said monitor/controller and having an air pressure responsive input and a corresponding pressure output signal;

a pneumatic tube with a mouthpiece engageable with the mouth of the patient for receiving the exhalation of a Valsalva maneuver performed by the patient;

means for determining the interval of said Valsalva maneuver; and

an electromagnetically operable pneumatic valve coupled with the pneumatic tube and switchable from a non-venting to a vent-to-atmosphere orientation when signalled by the monitor/controller;

wherein the monitor/controller is adapted to display the start and cue the release of the Vasalva maneuver and to cue the time of actuation of the indicator delivery system with respect to such Valsalva maneuver start and release.

4. The system of claim 1 in which:

the circulatory anomaly is one or more of a cardiac shunt, an atrial septal defect, a patent foramen ovale, a patent ductus arteriosus, a ventral septal defect, and a pulmonary arteriovenous malformation.

5. The system of claim 1 in which:

the indicator delivery system includes a flow sensor responsive to derive signals corresponding with the commencement and termination of fluid flow through the system; and

the monitor/controller is responsive to such commencement and termination signals to provide an audible alarm to the operator when the time interval of indicator injection is excessive.

6. The system of claim 1 in which the fluorescing biocompatible dye is one or more of indocyanine green dye, infracyanine green (IfCG) dye, another cyanine dye, methylene blue dye, trypan blue (TB) dye, patent blue (PB) dye, brilliant blue G (BBG) dye, lymphazurin blue dye, any of the various colors (Green, Yellow to Red, Far red and Near infrared, Blue) of Alexa Fluor dyes, sodium fluorescein (SF), a radioisotope, another radionuclear substance, or fluorescent nanoparticles.

7. The system of claim 1 in which the at least one sensor further comprises:

two or more paired excitation laser diodes and filtered photodetectors and the laser diodes being energizable in a sequence or simultaneously; and

an aspheric collimating lens, a collimator plate and an interference filter associated with each laser diode and located in the transmission path to the photodetector;

wherein the laser diodes are energizable to emit light at a wavelength of 785 nanometers; and

wherein the monitor/controller is responsive to select the laser diode-photodetector pair detecting a fluorescing output of highest intensity.

8. The system of claim 2 in which two sensors are present, the sensors comprising fluorescence sensing array fixtures with sensing array arms and being removably attached to a headband, and wherein a sensor is located at the schaphoid fossa of each ear of the patient.

9. The system of claim 1 in which:

the indicator delivery assembly comprises a flexible elongate delivery tube having proximal and distal ends, an auxiliary catheter coupled in fluid transfer relationship with the distal end defining the outlet, a indicator fluid flow detector coupled in fluid transfer relationship with the proximal end and deriving signals corresponding with the commencement and termination of fluid flow through the system, a three-way valve connected upstream to the fluid flow sensor, a first indicator containing syringe coupled in indicator flow relationship with the valve and actuatable to cause indicator to flow through the valve, and a second isotonic saline fluid containing syringe coupled in fluid flow relationship with the valve and actuatable to cause isotonic saline to flow through the valve; and

wherein the flexible elongate delivery tube is preloaded with a quantity of indicator from the first indicator containing syringe, the valve is actuatable to connect with the second isotonic saline fluid containing syringe, and upon actuation of the second syringe the fluid flow sensor signals will be transmitted to the monitor/controller; and

wherein the monitor/controller is responsive to cue an operator first to actuate the first syringe and immediately thereafter to actuate the second syringe, and is responsive to monitor the corresponding fluid flow sensor signals.

10. The system of claim 1 in which

the at least one non-invasive optical sensor further comprises a fixture having a laser diode array support and a photodetector array support, each of which extends outward from a base portion with a tissue-receiving gap therebetween;

a spring connecting the laser diode array support and a photodetector array support at the base portion thereof and biasing the laser diode array support and photodetector array support toward each other;

a protrusion extending from near a distal end of each of the laser diode array support and photodetector array support toward the tissue-receiving gap;

an array of three laser diodes and corresponding collimating lenses located within the protrusion of the laser array support and oriented to emit light toward the tissue receiving gap; and

an array of three photodetectors and a collimating lens and interference filter located within the protrusion of the photodetector array support, the photodetectors aligned with the laser diodes and oriented to receive light passing through the tissue receiving gap;

wherein the fixture can be placed in a clamped arrangement on the exterior of the patient bodyby compressing the spring to expand the tissue-receiving gap, placing subject tissue within the expanded tissue-receiving gap, and subsequently releasing the spring, thereby allowing the laser diode array support and photodetector array support to move toward each other and trap the tissue therebetween.

11. The system of claim 1 wherein the at least one sensor further comprises a control board located within the fixture, the control board in electrical communication with the laser diodes and photodetectors.

12. The system of claim 11 wherein the control board is programmed or otherwise adapted to sequentially operate the laser diode/photodetector pairs, such that only one laser diode/photodetector pair at a time is operational.

13. The system of claim 8 further comprising positionable wedges for positioning the sensors on the ear.

14. The system of claim 11 wherein the control board is programmed or otherwise adapted to repeatedly sequentially operate the laser diode/photodetector pairs over some predetermined period of time.

15. The system of claim 11 wherein:

the control board is programmed or otherwise adapted to determine which laser diode/photodetector pair detects the highest peak indicator photon fluorescence level during operation of the at least one sensor.

16. The system of claim 10 wherein:

the fixture is a clip that facilitates the temporary coupling of the sensor over a section of tissue associated with a body part selected from the group consisting of the pinna of the ear; the hand, including the web of skin between the thumb and forefinger; the neck, including distendable skin about the neck; the leg; and the arm, including distendable skin of the arm proximal to the shoulder.

17. The system of claim 10 further comprising:

an additional emitter located on the laser diode array support and an additional detector located on the photodetector array support;

wherein when the additional emitter and additional detector form an optical interlock when in sufficiently close proximity to one another, the optical interlock providing a signal useable by control circuitry with which the at least sensor is associated.

18. The system of claim 1, further comprising a kit of consumable materials necessary for detecting and quantifying a right-to-left cardiac shunt, the kit comprising:

a) an indicator delivery tubing system providing a valve, syringe connectors, a flow sensor and sterile intravenous injector;

b) one or more doses of circulatory indicator reagent as a shelf stable material;

c) a diluent for preparing the dose of circulatory indicator reagent for injection or for delivering an indicator bolus;

d) a dose of nonreactive blood compatible clearing reagent for completing the injection; and

e) a Valsalva mouthpiece apparatus with a mouthpiece and monitor connector coupling.

19. The system of claim 18 further comprising a single-use flow sensor having a circuit in communication with the monitor-controller, the circuit becoming disabled for repeat use after initiation of a testing procedure.

20. The system of claim 18 further comprising a sealed tray containing the kit contents in a sterile condition until opened.