Claims

Independent device claim

1. An inline monitoring assembly for an extracorporeal circuit, comprising:

a) a cuvette body (1) defining a serpentine flow-channel having an internal volume ≤ 0.6 mL and first and second ports configured for fluid communication with the circuit;

b) at least one micro-bore capillary inlet (2) intersecting the flow-channel, the micro-bore having an inner diameter ≤ 0.25 mm;

c) a sled pocket (3) formed in a wall of the cuvette body, the sled pocket dimensioned to receive a disposable electro-chemical test strip such that a reagent pad of the strip is in capillary-fed communication with the micro-bore;

d) at least two spring-loaded electrical contacts (4) disposed adjacent the sled pocket and arranged to engage contact pads on the test strip; and

e) wherein, when a dry test strip is seated in the sled pocket, capillary action alone diverts a sample volume not exceeding 1.2 µL from the flow-channel to the reagent pad while permitting a balance of bulk fluid to remain in continuous flow through the serpentine flow-channel.

Dependent structural claims

2. The assembly of claim 1, further comprising a plurality of sled pockets and a corresponding plurality of micro-bore capillary inlets, each sled pocket configured to receive a different electro-chemical strip chemistry.

3. The assembly of claim 1, wherein the cuvette body is fabricated from polymethyl-methacrylate and is surrounded by a thermally-conductive shoe (7) that carries a resistive heater (8) and a temperature sensor (10) for maintaining the test strip at 30 ± 0.2 °C.

4. The assembly of claim 1, wherein the internal volume of the flow-channel is ≤ 0.5 mL and a path length of at least 70 mm is provided to minimise shear.

Rotary-magazine embodiment

5. The assembly of claim 1, further comprising an indexing means (18, 19), disposed adjacent the sled pocket, the indexing means being configured to sequentially advance a plurality of test strips into the sled pocket at a predetermined time interval without operator intervention.

6. The assembly of claim 5, wherein the indexing means comprises a Geneva wheel (18) driven by a stepper motor (19) and an optical home-position sensor (20).

7. The assembly of claim 5, further comprising a chute (24) positioned to receive each test strip after use and a waste container coupled to the chute.

SIP refresh-flow embodiment

8. The assembly of claim 1, further comprising a fluid-refresh means (22, 23, 13) configured to deliver a trickle flow of sample fluid not exceeding 25 µL h^{-1} to a reagent pad of the test strip while the strip remains seated in the sled pocket.

9. The assembly of claim 8, wherein the fluid-refresh means comprises:

a restrictor line (22) having an inner diameter ≤ 0.33 mm;

a micro-pump (23) located outside the sterile flow-path; and

a manifold chamber (13) that distributes the trickle flow to multiple micro-bore capillary inlets.

System / software claim

10. A monitoring system comprising the assembly of claim 1 and a controller programmed to:

a) receive raw sensor signals from the test strip each sampling cycle;

b) apply a temperature correction and an adaptive first-order drift-compensation algorithm characterised by parameters α and τ;

c) output a drift-corrected analyte value; and

d) inhibit dosing and issue an alarm when a residual between predicted and measured signal exceeds 2 %.

Method claims

11. A method of continuously monitoring an analyte in an extracorporeal blood circuit, the method comprising:

a) passing blood through the serpentine flow-channel of the assembly of claim 1;

b) diverting, by capillary action alone, a microlitre-scale aliquot from the flow-channel to a dry electro-chemical test strip seated in the sled pocket;

c) measuring an electrical signal generated by the test strip;

d) correcting the signal for temperature and first-order drift; and

e) actuating a therapeutic device in response to the corrected analyte value.

12. The method of claim 11, wherein successive test strips are automatically advanced into the sled pocket at a fixed interval by the indexing means of claim 5.

13. The method of claim 11, wherein the test strip remains seated for at least six hours and receives a continuous trickle flow of 10–25 µL h^{-1} delivered by the fluid-refresh means of claim 8.

14. The method of claim 13, further comprising suppressing therapeutic actuation when the continuous trickle flow is below a predetermined threshold for more than five minutes.

Additional dependent claims

15. The assembly of claim 1, wherein the disposable electro-chemical test strip is FDA-cleared for at least one of glucose, lactate, β-hydroxybutyrate or creatinine in whole blood.

16. The assembly of claim 1, wherein the spring-loaded electrical contacts exert a normal force of 100–200 g against the contact pads.

17. The assembly of claim 5, wherein each indexing event disposes of the previously-used strip via gravity into the chute without line disconnection.

18. The assembly of claim 8, further comprising a flow sensor (14) positioned in the trickle line and coupled to the controller to validate that the refresh flow is within ±10 % of a set-point.

19. The assembly of claim 3, wherein the thermally-conductive shoe is copper and is coated with a biocompatible black-oxide finish.

20. The assembly of claim 1, wherein the cuvette body further comprises opposed optical windows permitting spectrophotometric analysis concurrently with electro-chemical strip measurement.
