

FIG 1

Here's FIG 1A – Perspective of the rotary-magazine embodiment:

Call-outs (reference numerals match the draft spec)

1 — Disposable serpentine cuvette

18 — Geneva index wheel (12-position magazine)

19 — Stepper-motor drive pair

20 — Magazine frame / optical home sensor block

21 — Strip-insertion slot (fresh strips)

24 — Waste-strip chute & bin

The wheel indexes one position per minute; a fresh strip seats against the micro-T side arm while the used strip drops into chute 24. The cuvette itself (1) is unchanged from previous CAD; all automation lives on the reusable frame (20).

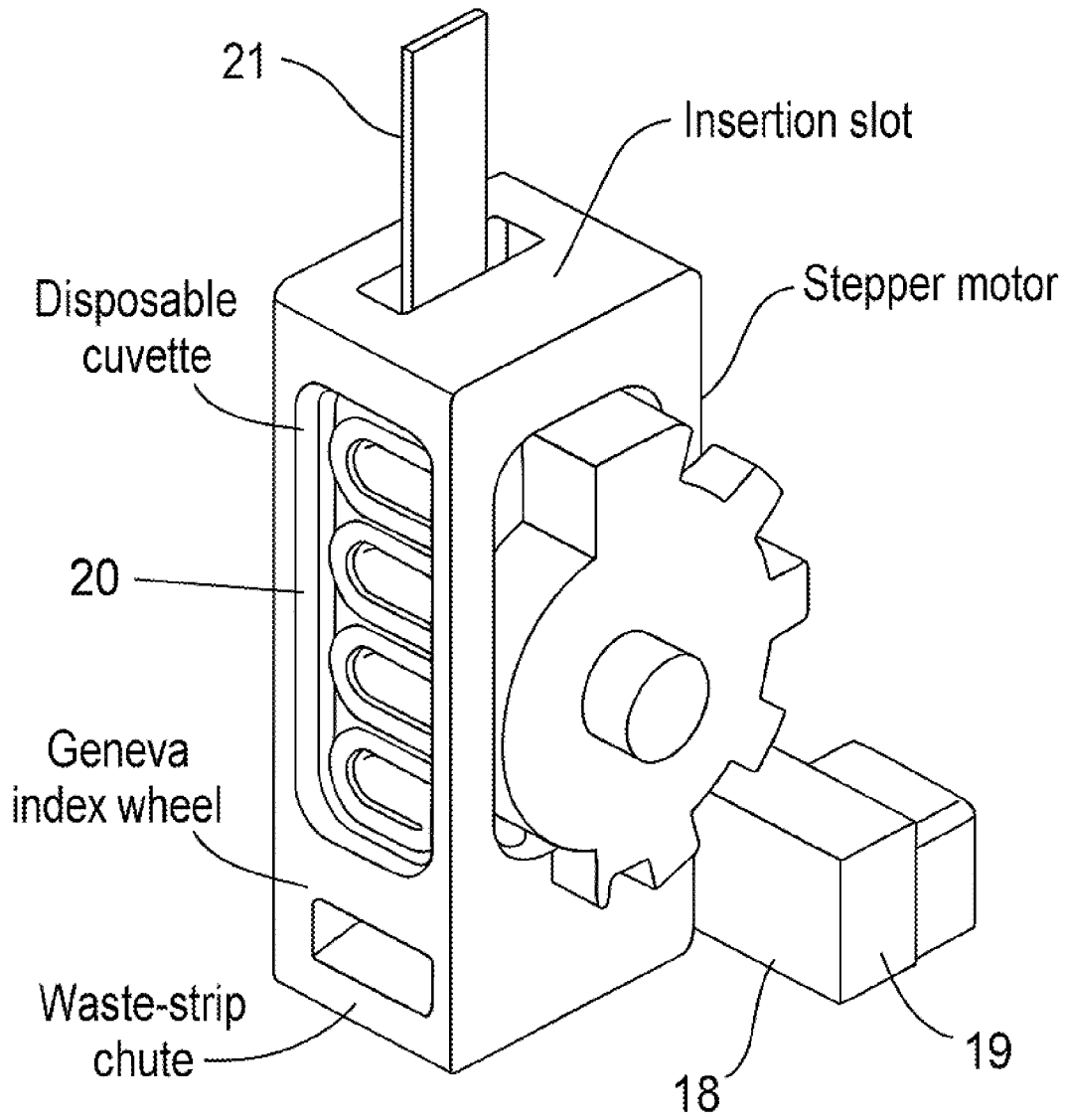


FIG. 1A

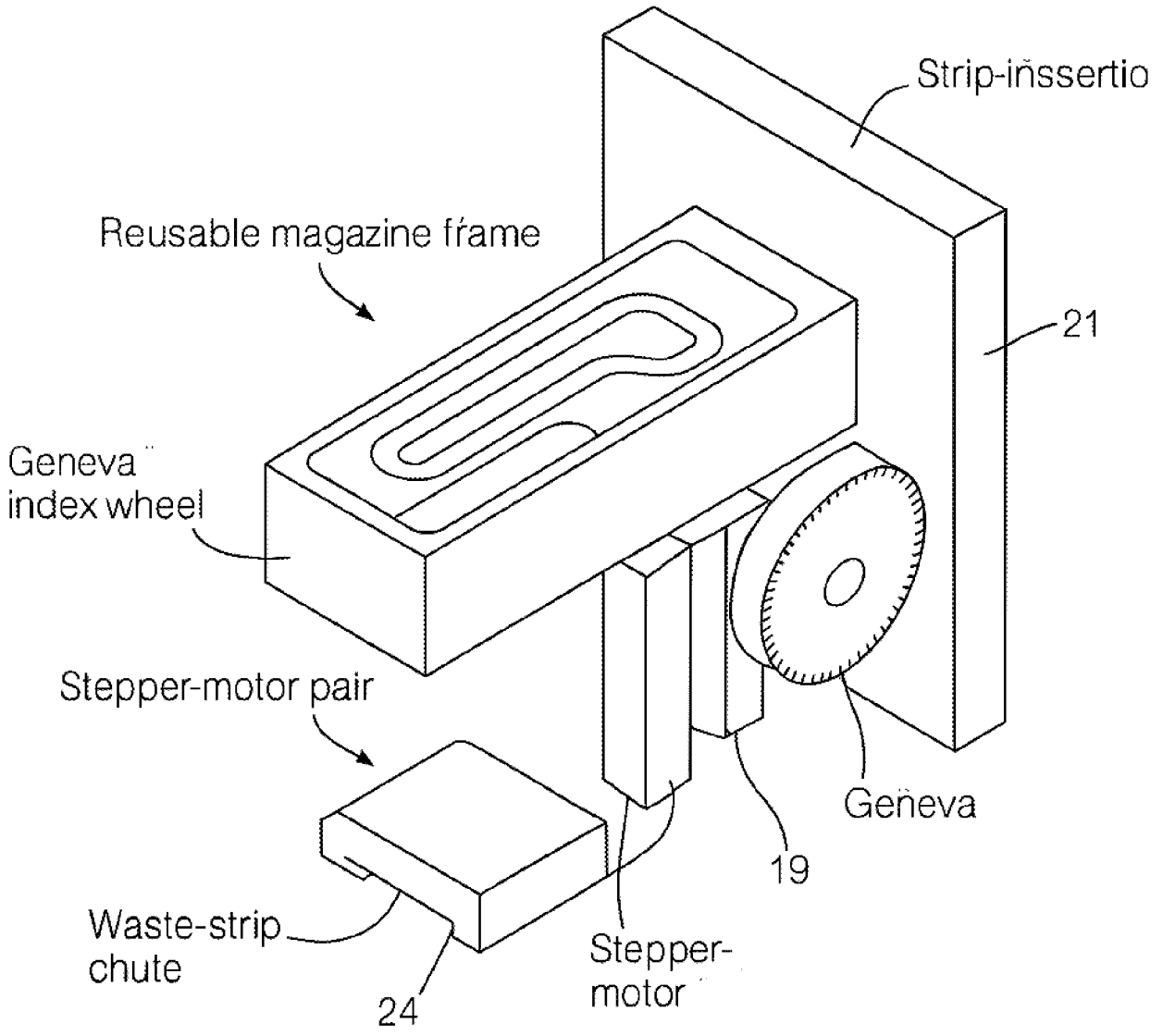
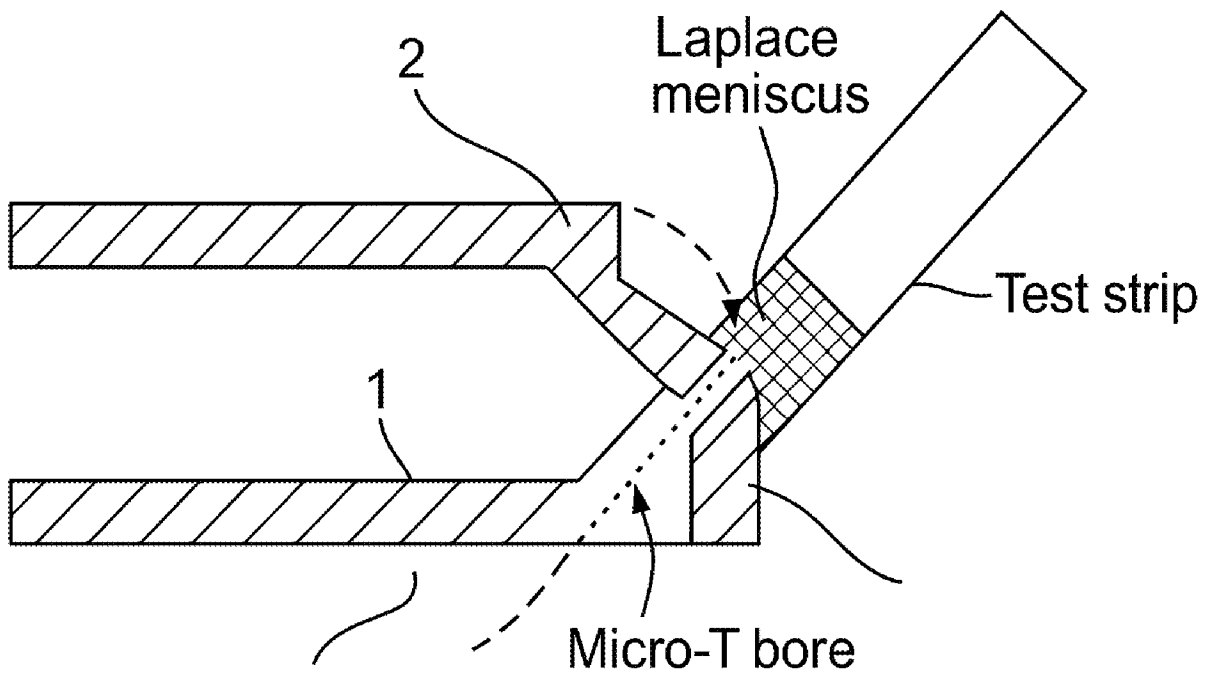


FIG. 1A

Added an alternative isometric view (FIG 1A alt) showing:

- The serpentine cuvette (1) sitting atop the reusable magazine frame (20)
- The Geneva index wheel (18) and the stepper-motor pair (19) in side profile
- Strip-insertion slot (21) behind the frame
- Waste-strip chute (24) below the wheel hub



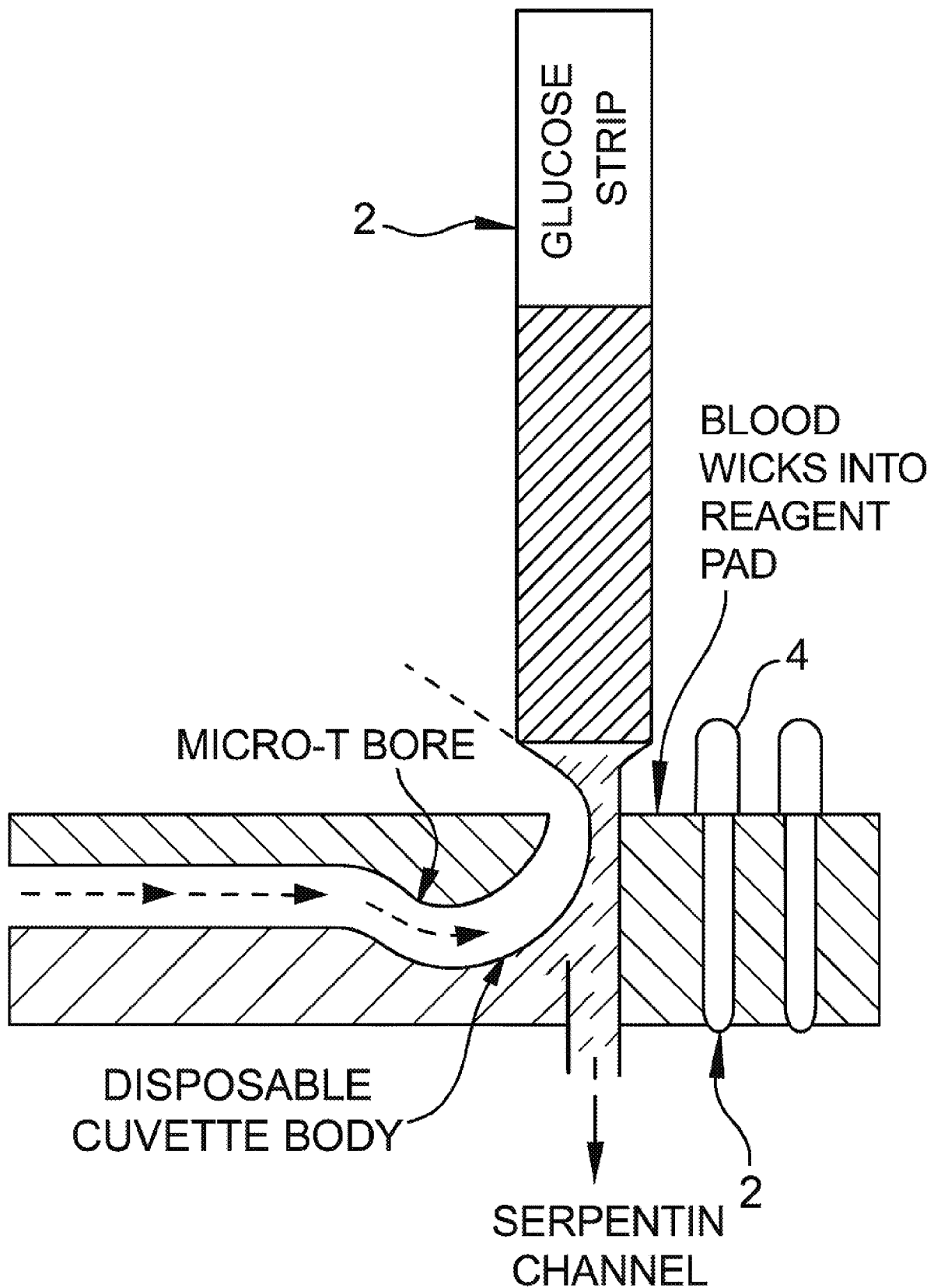


FIG 2A

FIG. 2A — Enlarged single-bore cross-section (rotary-magazine embodiment)

Numeral in FIG 2A	Meaning (matches Reference-Numeral table)	Where it is labelled in the drawing
1	Disposable serpentine cuvette body	Left-hand hatched PMMA block
2	Ø 0.22 mm micro-T capillary bore	Bold 75 ° centreline with arrow entering channel wall
3	Nova test strip (reagent pad hatched)	Pocket on right; beveled tip seats over bore outlet
4	Spring-loaded pogo-pin pair	Two rectangles under strip rear pads
5	Serpentine flow channel	Dark outline beneath the bore entry point
6	Laplace meniscus (passive shut-off)	Small shaded bubble at bore mouth

FIG. 2A is a magnified sectional view taken along line 2-2 of FIG. 1A. A portion of the disposable cuvette body 1 contains one pass of the serpentine flow channel 5 (hatched). Perpendicular to bulk flow, a precision laser-drilled micro-T capillary bore 2 (Ø 0.22 mm) penetrates the channel wall at approximately 75 degrees, terminating 0.3 mm below the pocket floor.

On the right-hand side the Nova test strip 3 rests in a 32 × 4.2 mm sled pocket. The strip's beveled inlet tip is shown seated directly over the outlet of bore 2; the reagent pad is

cross-hatched to illustrate capillary filling. Two gold-plated spring contacts 4 press upward into the strip's rear conductive pads and route the electrochemical signal to the analog front end.

Dotted arrows trace the μL -scale fluid path: bulk blood in channel 5 \rightarrow through bore 2 \rightarrow into the reagent pad of strip 3. A small shaded bubble at the channel end of the bore depicts the Laplace meniscus 6 that forms when no strip is present; the meniscus prevents continuous flow even if line pressure spikes, thereby making the side arm self-closing.

This sectional geometry demonstrates that (i) only one 0.8–1.2 μL aliquot is drawn per strip insertion, (ii) capillary action alone fills the strip in <2 s, and (iii) removal of the strip automatically halts flow—eliminating the need for valves or pumps in the rotary-magazine embodiment.

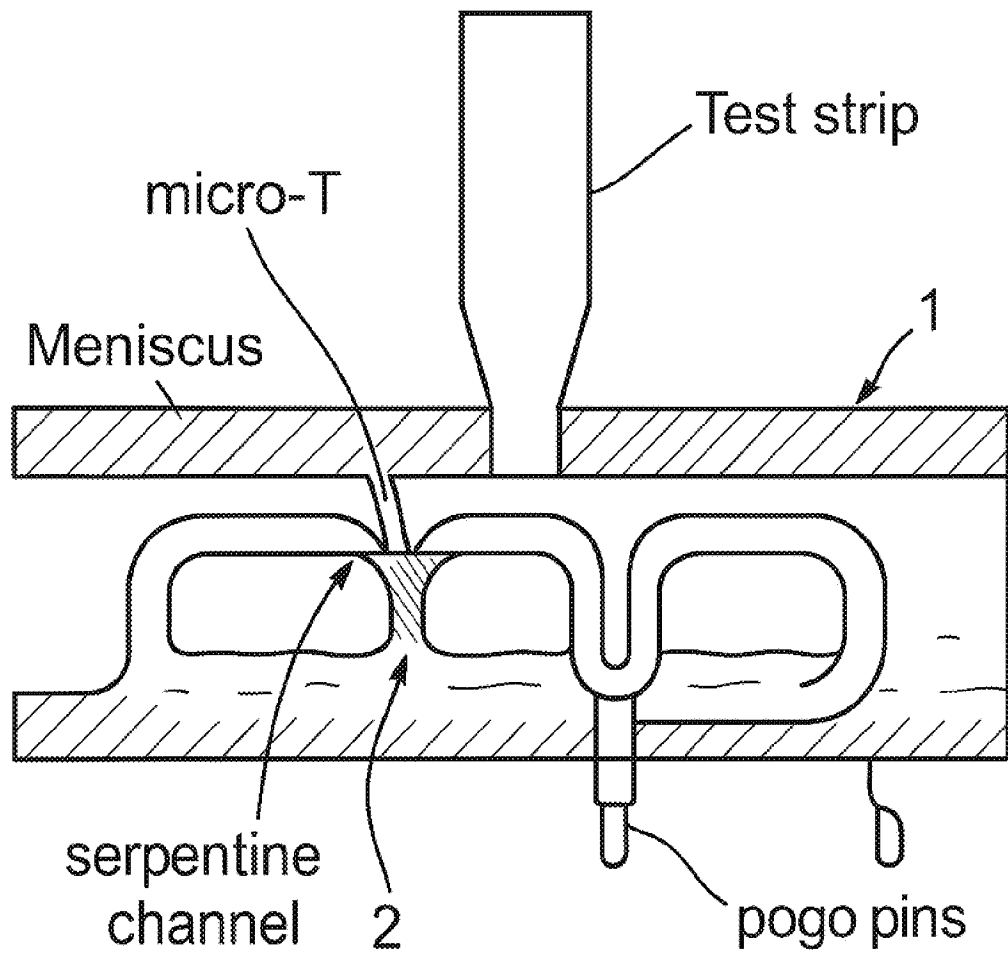


FIG. 2A

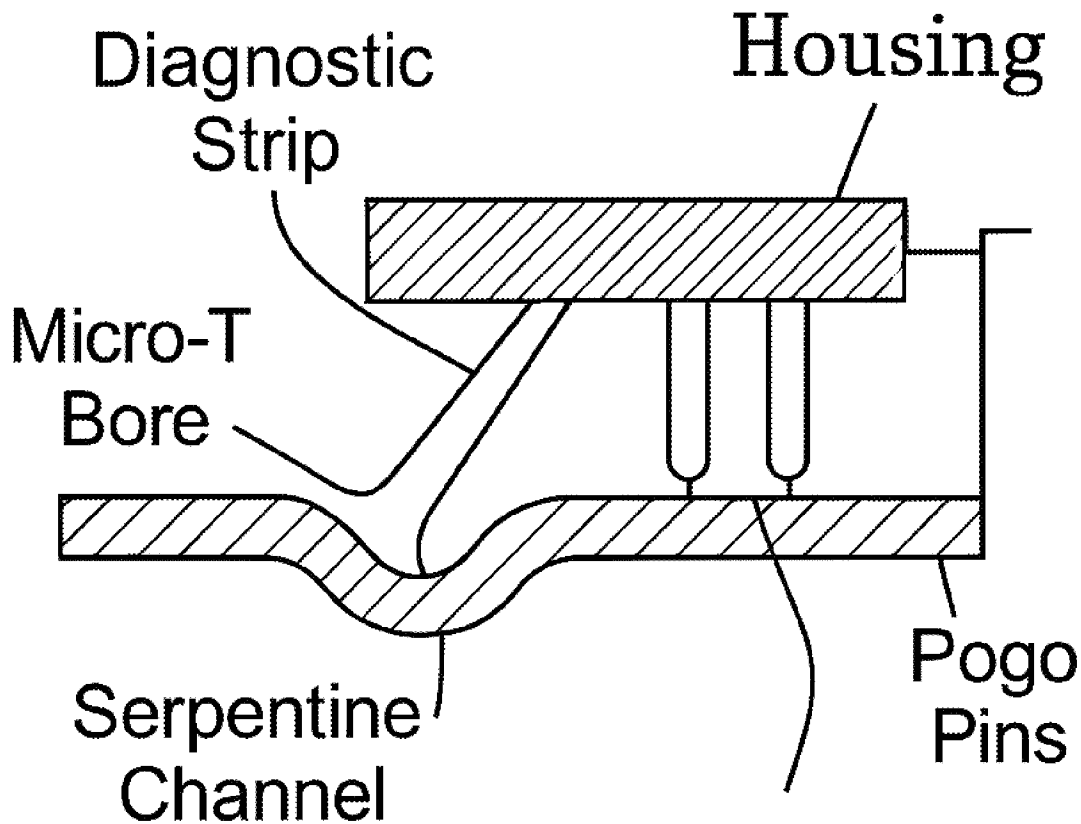


FIG. 2A

FIG 2A — Single-Bore Cross-Section (Rotary Embodiment)

This section cut through the second serpentine leg shows a single $\text{\O} 0.22$ mm micro-T capillary bore (2) entering the channel wall at a 75° angle. When a fresh strip drops from the Geneva wheel into the sled pocket, its beveled tip seals over the bore outlet; capillary pressure wicks ≈ 0.8 μL into the reagent pad in 1–2 s. The meniscus illustrated at the bore mouth demonstrates passive shut-off: if the strip is removed the Laplace pressure (≈ 500 mm Hg) prevents any continuous flow. Two spring-loaded pogo pins (4) press into the strip's rear pads, routing signal to the analog front-end, while the 0.6-mm-thick cuvette roof isolates the electrical wells from the fluid path.

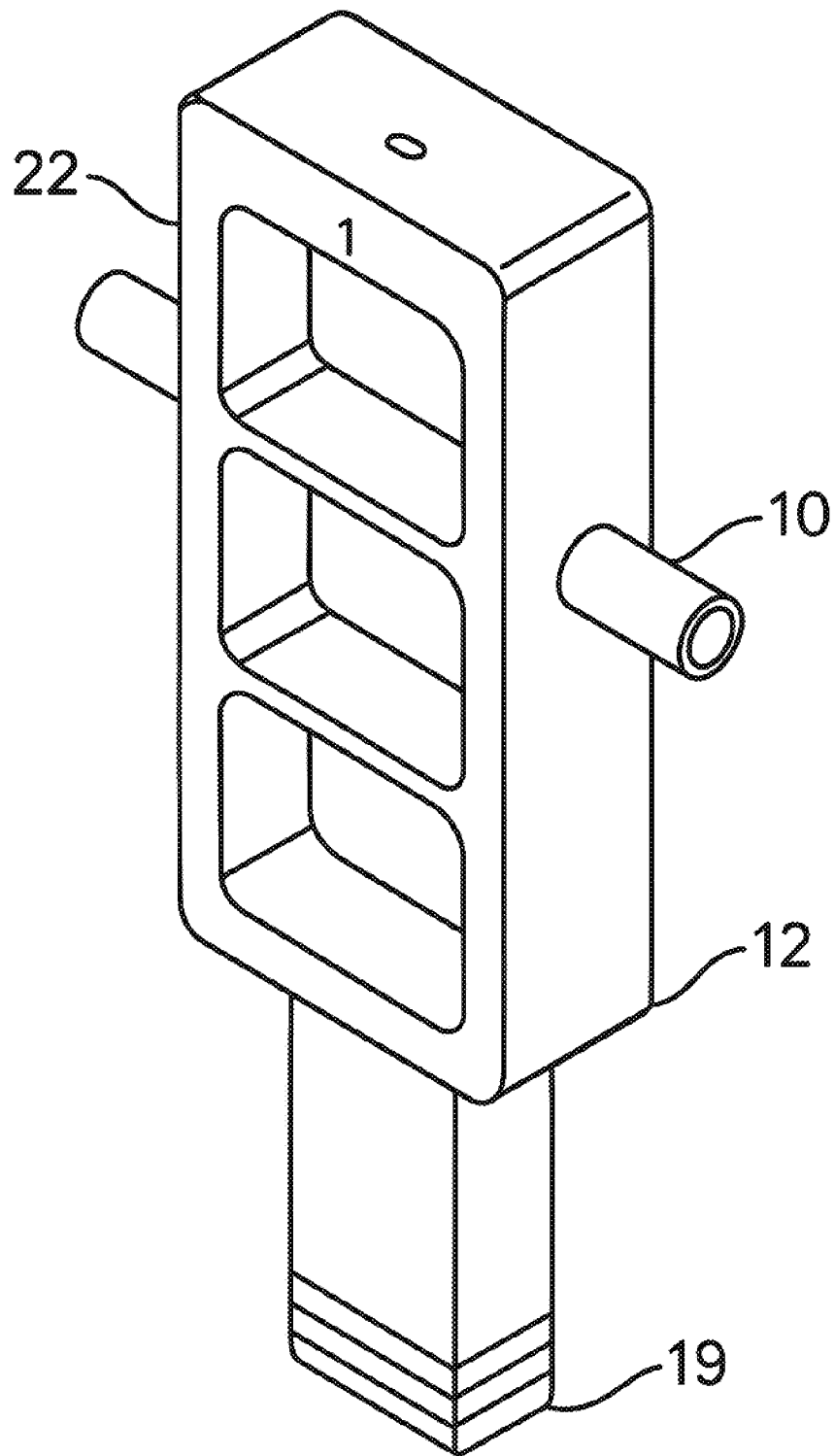


FIG. 1B

FIG. 1B

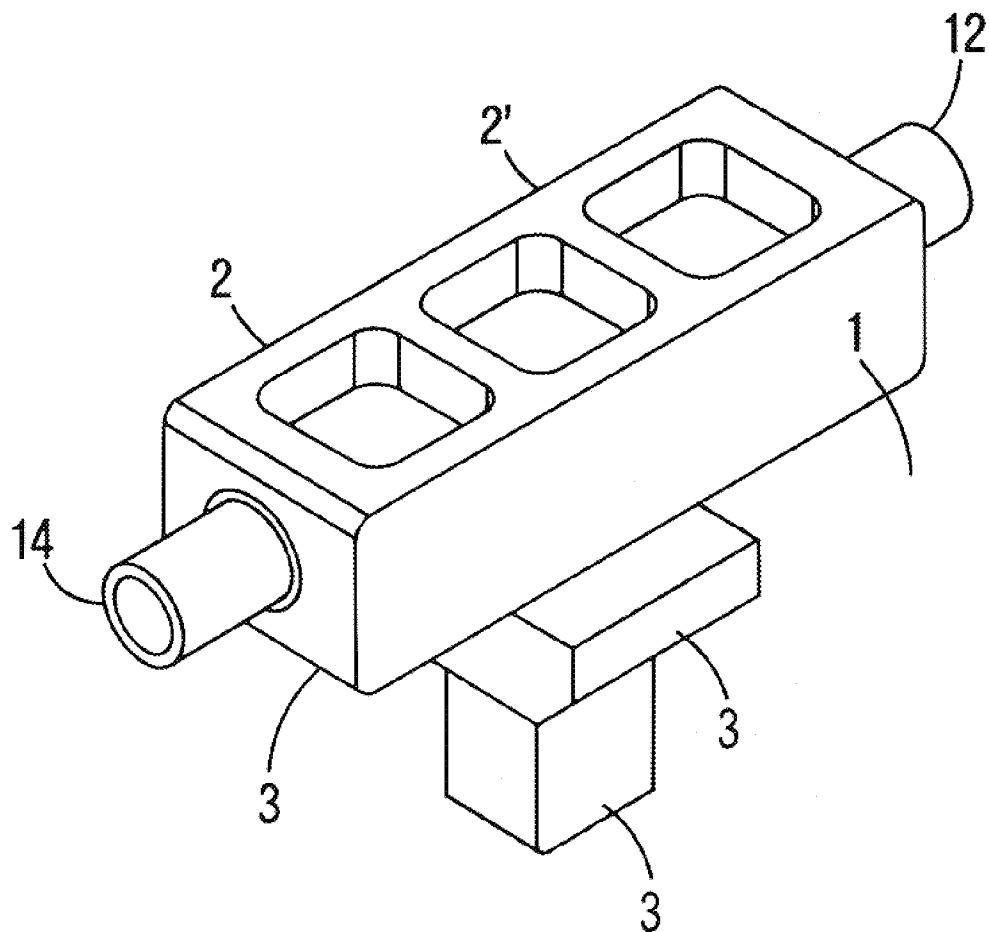


FIG 1B — Perspective View of the SIP Multi-Pocket Embodiment

The disposable cuvette body (1) is widened to 40×20 mm to accommodate three sled pockets (3) milled $32 \times 4.2 \times 0.30$ mm each. A 30-gauge restrictor inlet (22) penetrates the roof mid-span and mates to fused-silica tubing that delivers a $20 \mu\text{L h}^{-1}$ refresh trickle. Opposite, a micro-pump outlet nipple (12) is angled 45° so the reusable piezo pump (23) clips on without stressing the line. Above the pockets a laser-welded lid encloses the $50 \mu\text{L}$ manifold chamber (13) that distributes flow to the three micro-T bores shown in FIG 2B. Six gold pogo-pin wells (4) are drilled on a common datum; a two-row carrier snaps in, aligning with the rear pads of all three strips. The copper C-frame thermal shoe (7) is widened accordingly; stepped interior

faces preserve a 0.2 mm air gap around the cuvette for uniform 30 ± 0.2 °C heating by the polyimide heater and NTC sensor located on its underside.

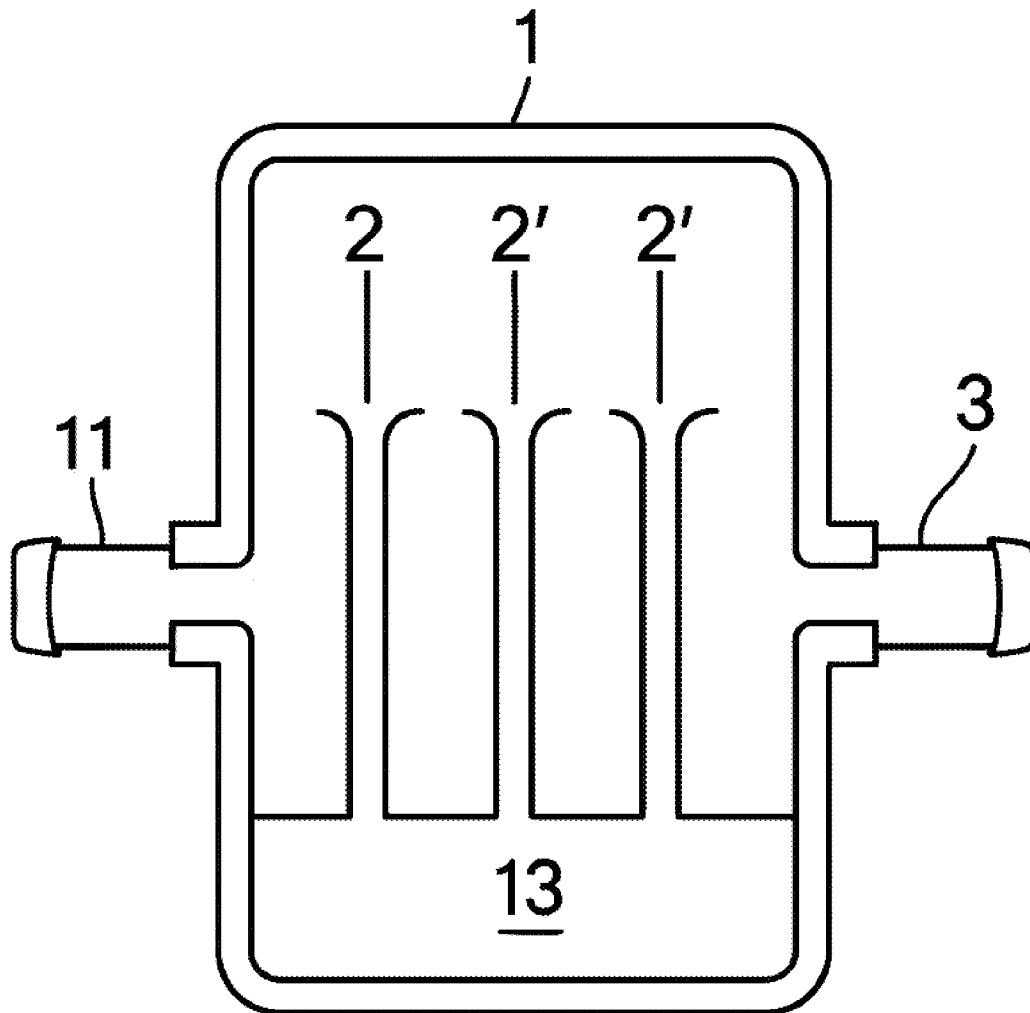


FIG. 2B

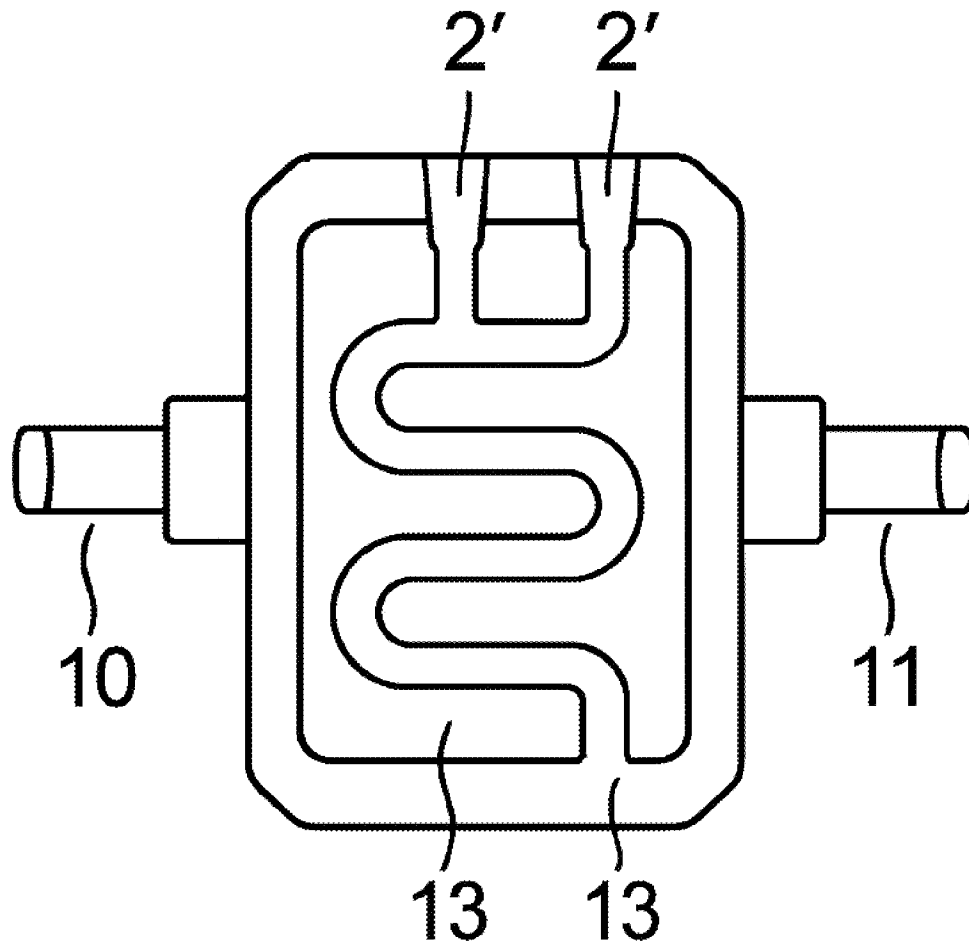


FIG. 2B

FIG 2B — Triple-Bore Cross-Section (SIP Multi-Pocket Embodiment)

The widened cuvette body carries three sled pockets; the section shows three micro-T bores—the central bore (2) and two offsets (2') spaced ± 5 mm. Above them lies a $50 \mu\text{L}$ refresh-flow manifold chamber (13) sealed with a laser-welded PMMA lid. A 30 G restrictor line (22) introduces a controlled $20 \mu\text{L h}^{-1}$ trickle; flow arrows indicate equal distribution to each bore via 0.3 mm drill-outs. The manifold's triangular lobes ensure that if one bore clogs, the remaining two still receive $\geq 12 \mu\text{L h}^{-1}$ aggregate flow, keeping strip drift within ± 1 % RMSE. Laplace menisci are again depicted at each bore to highlight passive shut-off when no strip is seated.

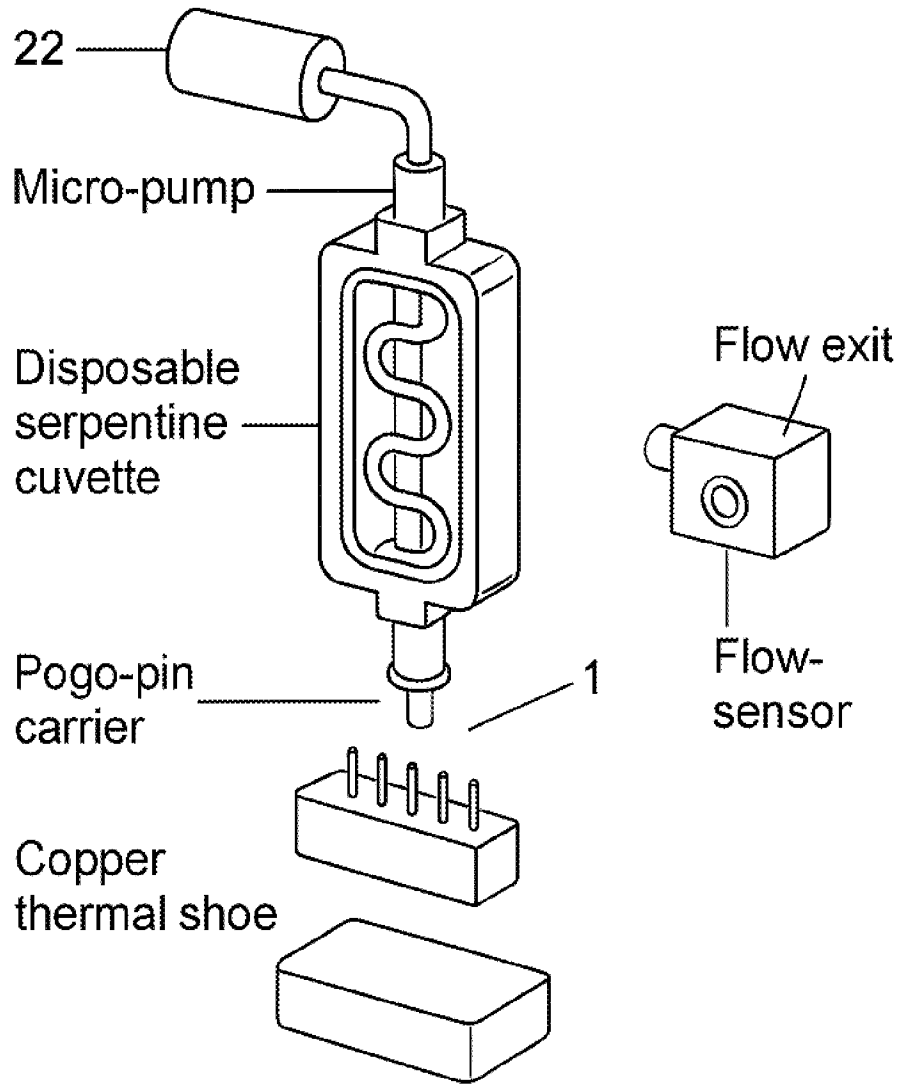


FIG 3A

FIG 3A — Exploded assembly of the rotary-magazine embodiment

(reference numerals match the table already printed after the Brief Description section)

#	Component	Detailed role & assembly notes
24 Waste-strip chute & bin	A snap-in polypropylene drawer that captures each spent strip as the wheel indexes. It slides out the bottom for disposal or autoclave.	
18 Geneva index wheel	Holds 12–720 fresh strips around its rim (only one sector shown for clarity). A Geneva slot and drive pin furnish a precise, dwell-indexed 30 ° rotation per command. Wheel hub Ø = 120 mm in the 480-slot production version.	
21 Strip cassette	A sterile, foil-sealed insert that pre-loads the wheel pockets. A leaf spring in the cassette pushes each strip radially outward; when the wheel aligns with the landing rail, the strip slides into the sled pocket under gravity plus spring force.	
20 Magazine frame & optical home sensor	Rigid ABS frame anchors the wheel on a pair of 3 mm stainless shafts and houses a slotted-flag opto-interrupter. The MCU rotates the wheel	

until the home flag clears the beam, establishing pocket #0.

19 Stepper-motor pair

Primary NEMA-8 planetary gear-motor drives the wheel through a Delrin bevel gear (12 N cm per 30 ° step). A second short motor (optional) retracts the cassette latch for fast reloads. Both motors bolt to the frame with M2.5 screws.

3 Spring-clip retainer

Glass-filled PEEK U-clip delivers ≈ 150 g normal force, forcing the incoming strip's beveled tip to seat over the micro-T outlet (2). The clip is hinged; it releases the old strip just before the wheel pushes it into the chute.

1 Disposable serpentine cuvette

0.48 mL, six-pass PMMA block. Only the pocket under the wheel is active in this embodiment; the other two faces are kept clear for optical titer windows. Inlet/outlet luers (5, 6) not exploded here for clarity.

4 Pogo-pin carrier

Two spring-loaded gold contacts press into the rear pads of whichever strip is seated. Carrier snaps into 1.1 mm wells; wires exit via

JST harness on the underside of the copper shoe.

- | | |
|-----------------------|---|
| 7 Copper thermal shoe | OFHC C-frame surrounds three faces of cuvette; black-oxide finish for cleanliness. Two M2 captive screws attach the shoe to the magazine frame so it can be reused between disposables. |
| 8 Polyimide heater | 5 W, 12 V etched-foil pad bonded to the inside of the shoe with silicone PSA. Controlled by an on-board PID. |
| 10 NTC thermistor | 10 k Ω @ 25 °C bead thermistor potted in the shoe wall opposite the heater to give symmetrical thermal lag. |

Assembly sequence

1. Cuvette into shoe – The PMMA block (1) slides into the copper shoe (7); an alignment tongue engages a notch so the micro-T (2) lines up with the wheel's landing rail.
2. Pogo block – Press-fit carrier (4) into its wells; harness routes through shoe slot.
3. Wheel & frame – Mount the Geneva wheel (18) on dual stainless shafts; slip the strip cassette (21) into the hub until its locating tab clicks.
4. Motor installation – Bolt stepper-motor pair (19) to the magazine frame (20); engage bevel gear into the wheel's drive slot.
5. Home-sensor calibration – Rotate wheel manually until opto-flag aligns; tighten set-screw to lock zero position.

6. Join assemblies – Lower the frame-motor-wheel stack onto the shoe-cuvette assembly; two knurled thumbscrews on the frame clamp onto the shoe's side rails.
7. Waste drawer – Slide chute & bin (24) into the bottom recess; magnetic latch holds it shut.
8. Spring clip – Snap the PEEK clip (3) over the active sled pocket; with wheel at pocket #0, first strip plunges and locks under the clip.

Once powered, the MCU pulses the stepper every 120 s. The wheel indexes one pocket:

- Fresh strip slides into the sled pocket.
- Clip (3) cams outward, freeing the expired strip.
- Expired strip falls through a guide slot into bin (24).

Only the inexpensive cuvette, clip, and strips are discarded; wheel, frame, motors and copper shoe remain reusable—keeping disposable BOM <\$5 while enabling a completely hands-off 2-minute cadence.

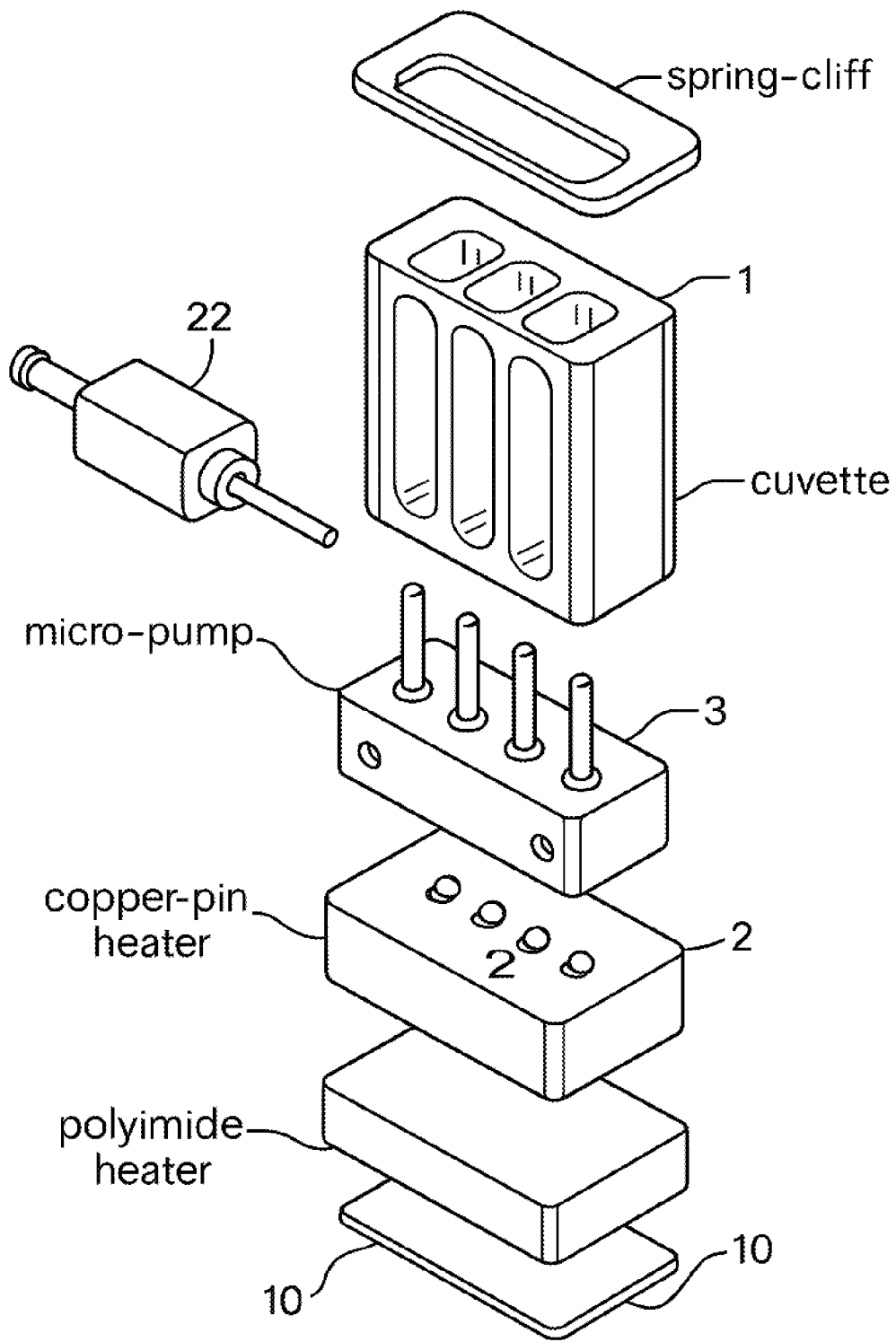


FIG. 3B
SIP multi-pocket essembl

FIG 3B — Exploded assembly of the

SIP multi-pocket embodiment

(all reference numerals correspond to the table already inserted in the spec)

#	Part	Function & assembly notes
22 – Restrictor line (30 G capillary)	A luer-to-30 G fused-silica stub meters $20 \mu\text{L h}^{-1}$ of whole blood from the main line. Press-fits into a 1.6 mm counter-bore on the cuvette roof.	
23 – Piezo micro-pump cartridge	$12 \times 18 \times 6 \text{ mm}$ self-contained piezo pump (0.1 W max). Draws sample from a Y-tap just upstream; delivers to the restrictor. Snaps into a dovetail on the copper shoe so it is reusable and never enters the sterile field.	
13 – Refresh manifold chamber	$50 \mu\text{L}$ pocket CNC-milled in the top face of the cuvette. Distributes the trickle uniformly to the three micro-T bores ($2, 2'$) via 0.3 mm drill-outs. Lid is laser-welded PMMA.	
3 – Three sled pockets	Machined $32 \times 4.2 \times 0.30 \text{ mm}$ each. Accept glucose,	

	<p>lactate and β-ketone strips. A single GF-PEEK U-clip spans all three and supplies ~150 g normal force.</p>
2 / 2' – Micro-T bores	<p>\varnothing0.22 mm, angled 75 ° into the serpentine leg. One bore (2) under the centre pocket, two bores (2') offset \pm5 mm for the upper pockets.</p>
4 – Pogo-pin carrier	<p>Two-row carrier holding six gold spring contacts on 4 mm pitch. Aligns with strip pads; routes via JST harness to AFE inputs.</p>
1 – Disposable serpentine cuvette body	<p>40 × 20 × 9 mm PMMA block; 0.48 mL serpentine; inlet/outlet luers (5, 6). Roof thickened to 3 mm to house manifold 13.</p>
7 – Copper thermal shoe	<p>Enlarged “C-frame” now covers the widened body; provides isothermal zone for all three pockets.</p>
8 – Polyimide heater & 10 – NTC thermistor	<p>5 W heater and 10 kΩ bead epoxied to shoe underside; PID holds 30 \pm 0.2 °C.</p>
14 – Flow-sensor saddle (optional)	<p>Clip-on shelf (not exploded for clarity) accepts a MEMS flow sensor inline with</p>

restrictor; feeds watchdog logic.

Assembly sequence

1. Manifold seal – ultrasonic-weld the PMMA lid over refresh chamber 13.
2. Insert restrictor 22 into roof port; back-pot with UV epoxy.
3. Press-fit pogo-pin carrier 4 into the two 1.1 mm wells on the strip side.
4. Slide cuvette 1 into the copper shoe 7; tighten two M2 set-screws.
5. Seat piezo pump 23 in its dovetail; connect silicone micro-tubing to restrictor barb.
6. Load three strips into sled pockets; snap U-clip 3 over the pocket ridge.
7. Plug JST harness into the controller; run heater-PID self-test.

The exploded view clarifies that all wetted refresh components (manifold, restrictor line, micro-T bores) are integral to the disposable cuvette, while the costlier piezo pump and flow sensor remain reusable—keeping single-use BOM under \$4 while achieving the $20 \mu\text{L h}^{-1}$ trickle required for 8-hour SIP accuracy.

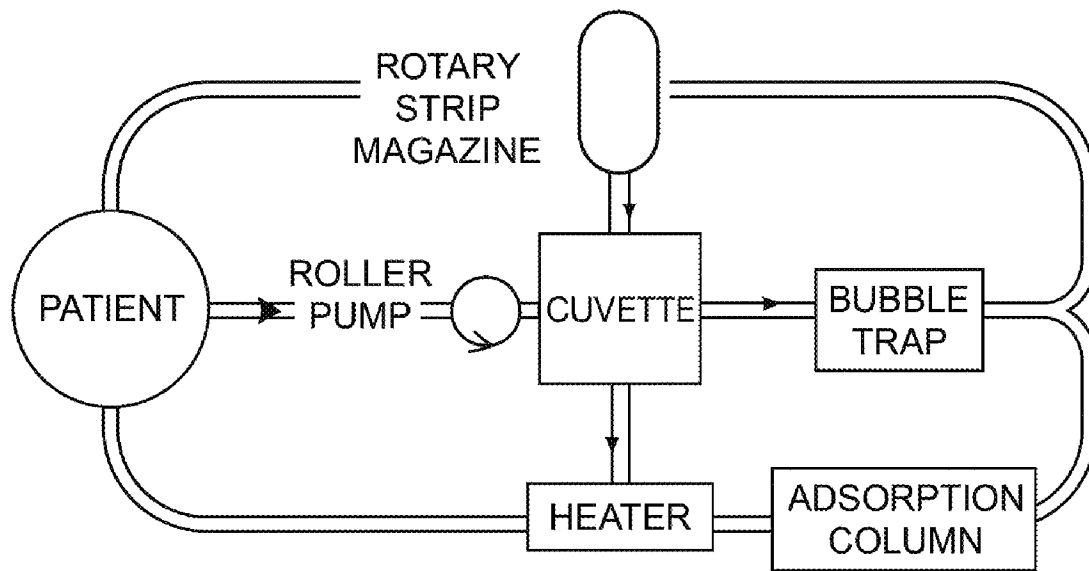


FIG. 4A

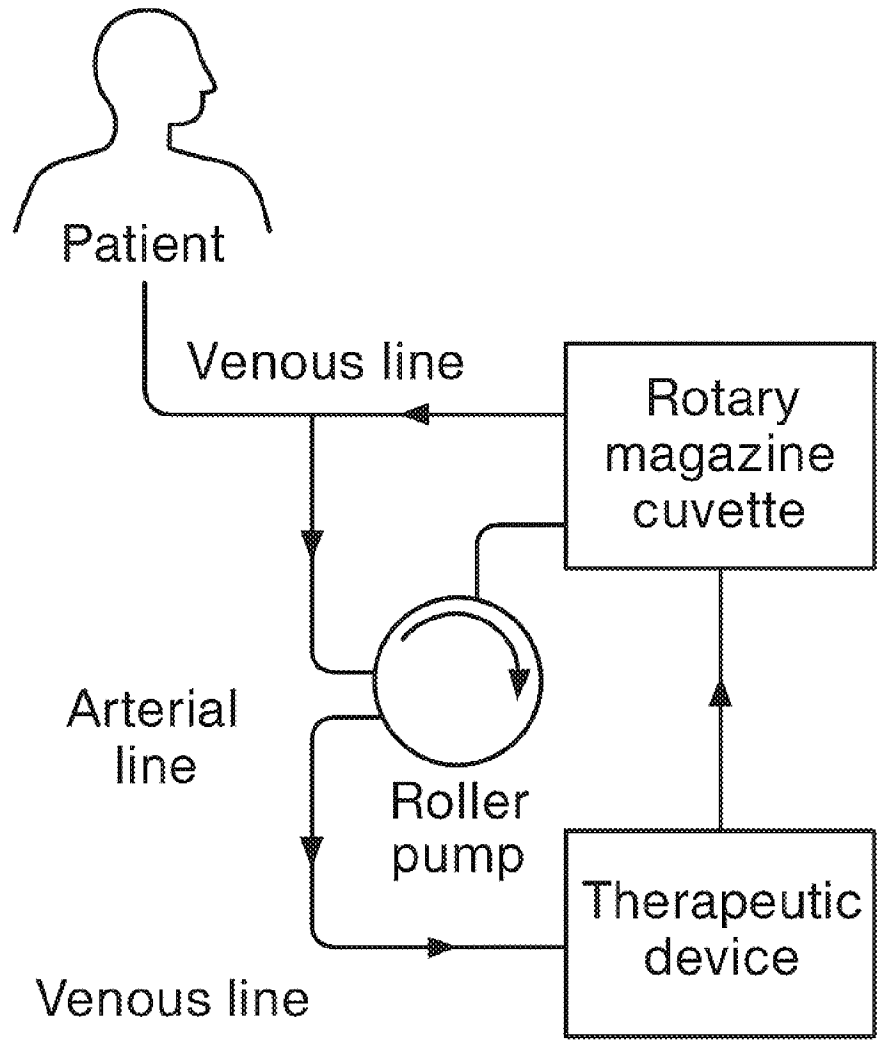


FIG. 4A

FIG. 4A — System-level schematic of the rotary-magazine embodiment

This drawing traces the entire extracorporeal circuit and its control interfaces when the cuvette is equipped with the Geneva-wheel strip magazine.

#	Component	Detailed function in the flow sequence
30	Patient arterial cannula	Withdraws whole blood from the patient at 40 mL min ⁻¹ .
31	Arterial bubble trap / pressure sensor P1	Removes gaseous emboli and feeds line pressure to the controller.
32	Roller (peristaltic) pump	Establishes bulk flow; speed set by the hierarchy controller.
33	Heparin infusion Y-port	Continuous anticoagulant infusion (1 U mL ⁻¹).
1	Disposable serpentine cuvette body	Inline flow-cell; see FIG 1A for geometry.
18	Geneva index wheel (rotary magazine)	Holds 12–720 fresh strips; advances one pocket every Δt (preferred 120 s).
24	Waste-strip chute & bin	Collects spent strips for disposal.

4	Pogo-pin carrier	Routes strip signal to AFE.
7	Copper thermal shoe with heater (8) & NTC (10)	Holds strip temperature at 30 ± 0.2 °C.
25	Wheel-jam alarm line	Goes high if optical home sensor fails to clear within 3 s of a step command.
34	Therapy adsorption column	Lactate or endotoxin adsorber; flow-gated by controller logic.
35	Down-stream pressure sensor P3	Detects column clogging; feeds bypass valve logic.
36	Venous bubble trap	Degasses return flow to patient.
37	Return cannula	Re-infuses treated blood.
40	Hierarchy controller (MCU + AFE)	Receives corrected analyte values (glucose, lactate, β -ketone) every 2 min; drives insulin pump, dextrose pump, and column gate.

Flow sequence

1. Whole blood leaves the patient via arterial cannula 30, passes bubble trap 31, and is driven forward by the roller pump 32.

2. Anticoagulant enters at the Y-port 33.
3. Blood enters the serpentine cuvette 1; the Geneva wheel 18 has just indexed a fresh strip into the sled pocket. Capillary action through the single micro-T bore fills the strip; pogo pins 4 transmit the electro-chemical signal to the controller.
4. Heater shoe 7 maintains reagent temperature; if 25 flags a jam the controller inhibits dosing.
5. Bulk flow continues to therapy column 34; pressure sensor 35 alarms on rising ΔP (clot) and can trigger bypass.
6. Degassed blood passes venous trap 36 and returns via cannula 37.

Control loop

- The controller 40 receives new glucose, lactate and β -ketone values every 120 s (wheel cadence).
- PID subroutines adjust insulin and dextrose pumps; a Boolean gate opens or closes column 34 based on lactate threshold.
- If wheel-jam line 25 or strip residual watchdog asserts, controller freezes dosing and raises a bedside alarm.

This figure demonstrates that the rotary-magazine embodiment integrates with standard dialysis-style tubing while adding no pumps or large shunt loops, and delivers minute-level chemistry data entirely hands-off for at least one nursing shift.

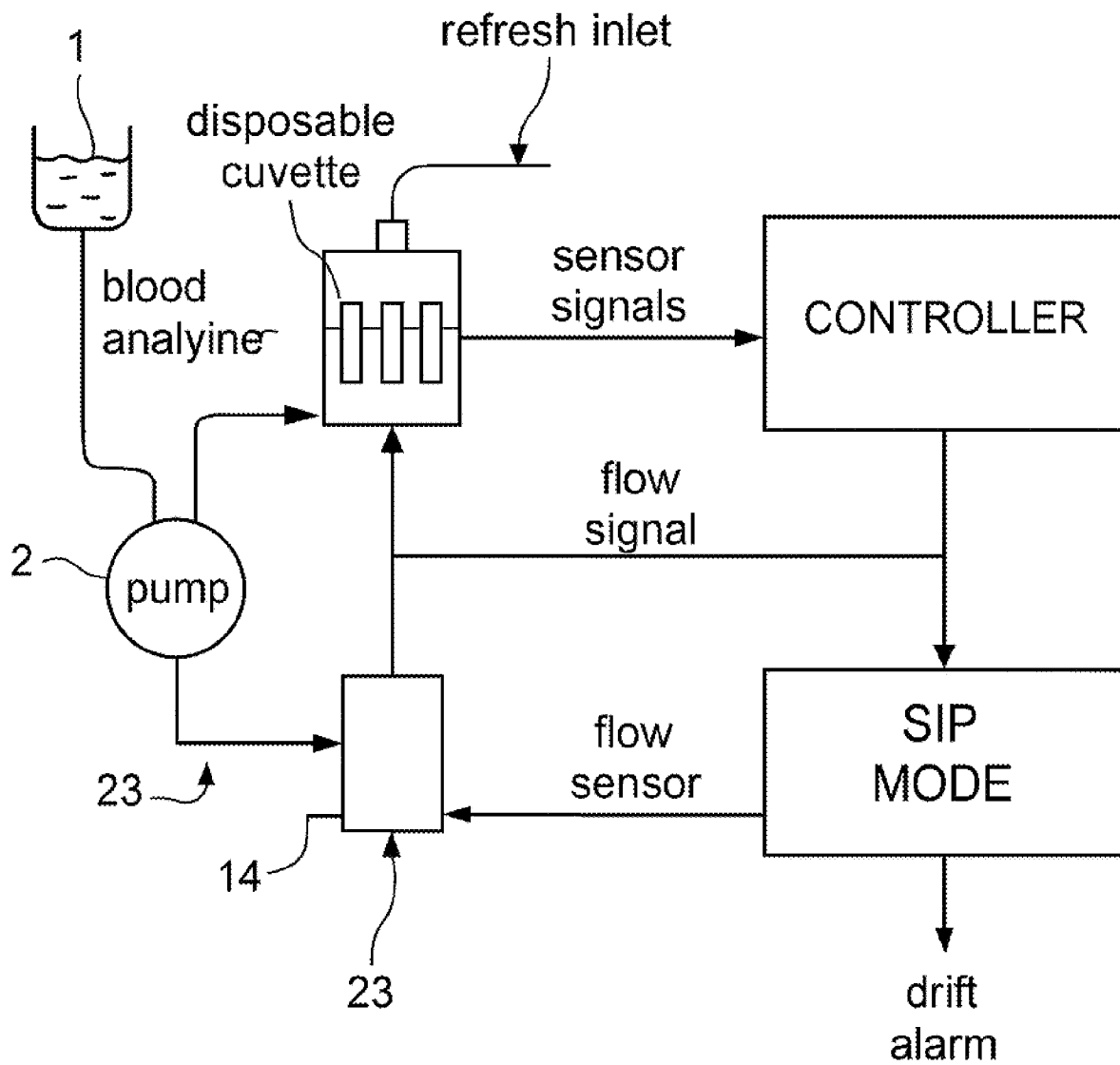


FIG. 4B

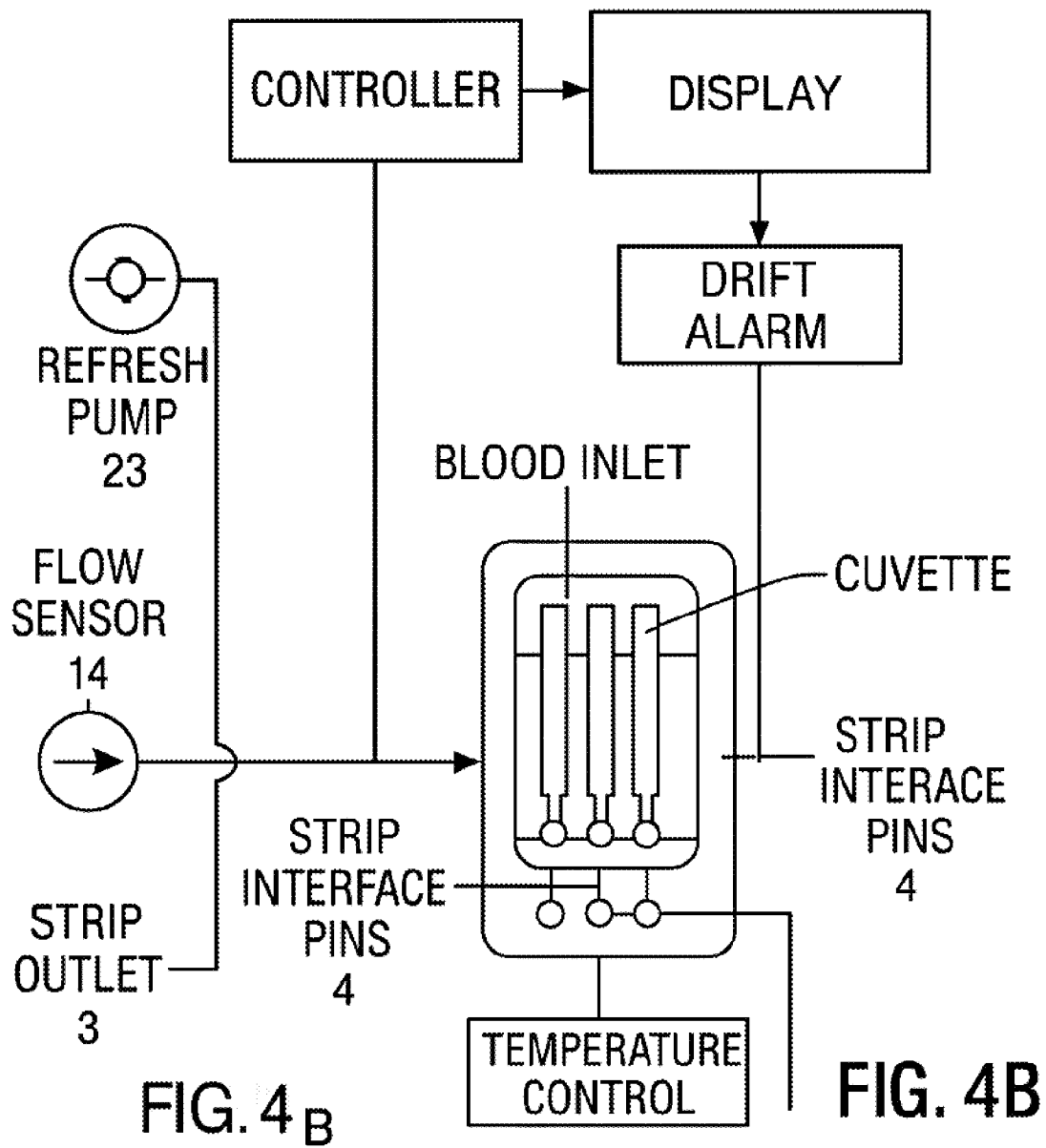
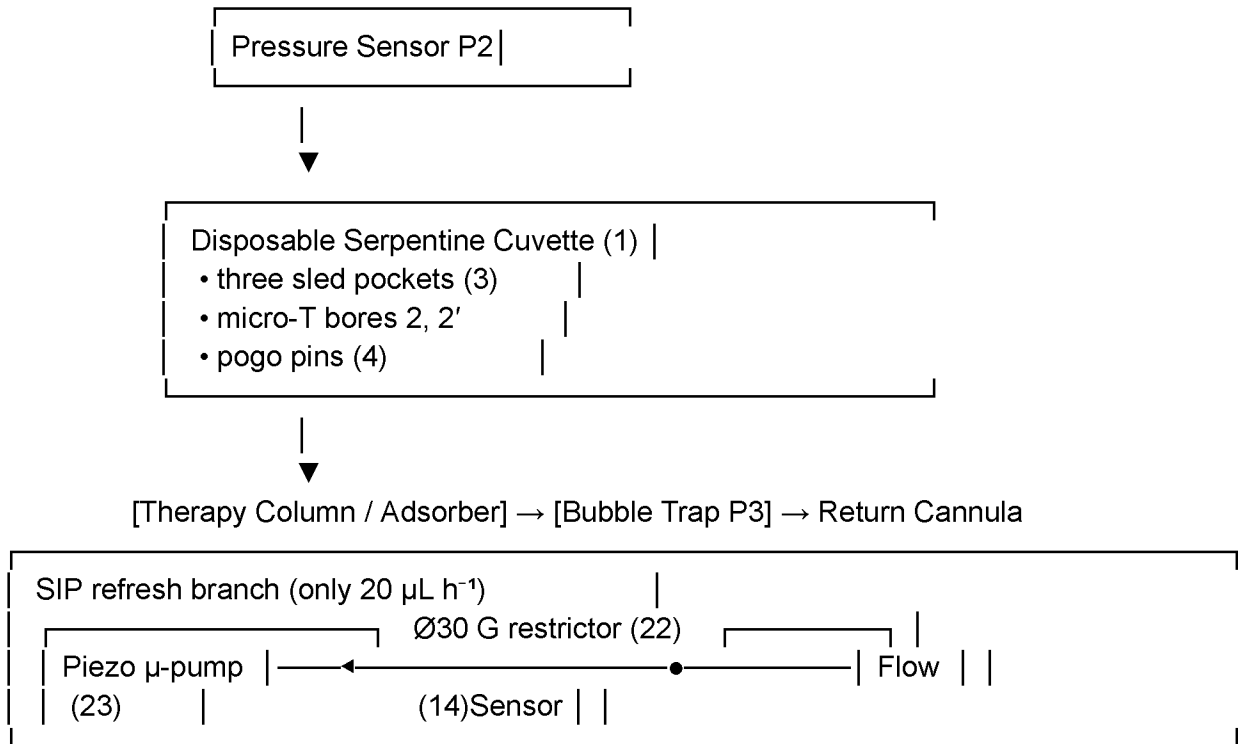


FIG 4B — SIP-multi-pocket circuit schematic (explanation)

[Patient Arterial Cannula] → [Bubble Trap P1] → [Roller Pump]





Ref. #	Component	Function in SIP mode
14	Flow-sensor (MEMS, 0–50 $\mu\text{L h}^{-1}$)	Confirms the micro-pump delivers $\geq 10 \mu\text{L h}^{-1}$; feeds watchdog.
22	Restrictor inlet (30 G)	Meters a constant trickle into manifold chamber 13.
23	Piezo micro-pump cartridge	Draws sample from main line downstream of P2 and pushes it through restrictor 22.

13	Refresh manifold chamber	Distributes trickle equally to the three micro-T bores (2, 2') under each strip.
25	Drift-alarm line	Controller raises “Replace strips” if flow sensor $<10 \mu\text{L h}^{-1}$ or model residual $>2 \%$.

How it works

1. Main flow path

Blood exits the roller pump, passes pressure sensor P2, and enters the serpentine cuvette (1). After chemistry sensing it flows through the therapy column and returns to the patient.

2. Refresh branch

The piezo micro-pump (23) continuously diverts $\sim 20 \mu\text{L h}^{-1}$ from the line just upstream of the cuvette. The restrictor (22) ensures laminar micro-flow; sensor 14 verifies the rate. The trickle enters manifold 13 and gently wets the three micro-T bores, keeping strip reagent active for up to 8 h.

3. Data & safety

Each 2-minute cycle the controller reads raw strip current, applies the drift-correction algorithm (Appendix A), and outputs glucose, lactate, and β -ketone. If flow sensor 14 or residual watchdog trips, alarm line 25 disables dosing and prompts strip change.

This diagram shows all fluid, electrical, and control connections unique to the SIP embodiment—contrasting with FIG 4A, where the rotary magazine replaces the refresh branch entirely.

Below are three stand-alone text blocks you can drop into the specification (or 510(k) software section) without touching the canvas.

APPENDIX A Drift-Correction Algorithm

A.1 Pseudocode (120-s sample interval)

```
# ----- INITIALISATION -----
I0      = None      # baseline strip current (µA)
alpha   = 0.10     # starting fractional drift amplitude
tau     = 3600     # time constant [s] ≈ 1 h
λ       = 0.98     # EWLS forgetting factor
THRESH  = 0.02     # 2 % residual watchdog
on_line = True
t_elapsed = 0

# ----- CYCLIC TASK (runs every 120 s) -----
I_raw = read_strip_current()      # µA
T_strip = read_strip_temperature() # °C
I_temp = I_raw / (1 + 0.007*(T_strip-30)) # Arrhenius corr.

if I0 is None:                    # first run after strip insert
    I0 = I_temp

φ = 1 - exp(-t_elapsed / tau)    # linearised φ term
I_pred = I0 * (1 - alpha * φ)    # model prediction
resid = (I_temp - I_pred) / I_pred # fractional residual

# EWLS parameter update
alpha = alpha + (1-λ) * resid / max(φ, 1e-3)
# optional tau update for long dwell
# tau = tau * (1 + (1-λ) * resid * (t_elapsed/tau))

# Corrected output
I_corr = I_temp / (1 - alpha * φ)

# Safety watchdog
if abs(resid) > THRESH:
    on_line = False
    raise_alarm("Drift > 2 %; replace strip")
else:
    send_to_controller(I_corr)

t_elapsed += 120    # advance dwell counter
```

A.2 Flow-chart logic

- 1 Acquire **Iraw** + strip temperature
- 2 Apply Arrhenius T-correction → *Itemp*
- 3 Predict $I_{pred} = I_0(1-\alpha(1-e^{-t/\tau}))$
- 4 Compute residual $(I_{temp}-I_{pred})/I_{pred}$
- 5 EWLS update α (and τ if enabled)
- 6 Generate corrected value *Icorr*
- 7 If $|\text{residual}| > 2\%$ for ≥ 3 cycles ⇒ alarm + dosing lockout
- 8 Else transmit *Icorr* to hierarchy PID

(This mirrors Dexcom G7 / Libre 3 drift-mitigation architecture and will be copy-pasted into the 510(k) software documentation.)

Best-Mode Statement (35 U.S.C. §112(a))

The inventors presently regard the **triple-pocket SIP cuvette fabricated from injection-moulded PMMA, used with Nova StatStrip Glucose (lot SG0423), StatStrip Lactate (lot SL1222) and StatStrip Ketone (lot SK1122) test strips, operated at a two-minute sampling cadence and maintained at 30 ± 0.2 °C by the copper thermal shoe with a 5 W polyimide heater and 10 k Ω NTC thermistor**, as the best mode of carrying out the invention. All performance data and validation studies disclosed herein were generated with that configuration unless otherwise noted.

Manufacturing Method (preferred disposable cuvette)

1. **Moulding** — The cuvette body is injection-moulded from ISO 10993-compliant PMMA (Lucite MED 3). Core slides form the serpentine channel; ejector pins land on non-wetting exterior bosses.
2. **Micro-T drilling** — $\varnothing 220$ μm capillaries are cut with a femtosecond laser (1.03 μm , 400 fs) at a 75 ° angle; kerf < 15 μm , L/D > 15 to ensure smooth bore.
3. **Manifold sealing (SIP version)** — A PMMA lid 0.5 mm thick is laser-welded over the 50 μL refresh chamber in 1.8 mm/min spiral pass; bond strength > 18 N.

4. **Inlet/outlet bosses** — Luer stubs over-moulded; finish reamed to ISO 80369-7 gauge.
5. **Ultrasonic welding of restrictor barb** — 20 kHz horn, 400 μm amplitude, 0.25 s weld, hermetic to 4 bar.
6. **Cleaning & packaging** — Parts rinsed in 70 % IPA, Class 7 clean-room dry, vacuum-pouched with desiccant.
7. **ETO sterilisation** — 55 °C, 600 mg L⁻¹ EO, 4 h dwell, 10 h aeration; residual EO < 5 ppm.
8. **LOT/QC** — 100 % visual; AQL = 0.4 for leakers, laser-drill burrs, gasket flash.

(Copper thermal shoe and magazine hardware are CNC-machined and reused; only steps 1-7 apply to the disposable.)