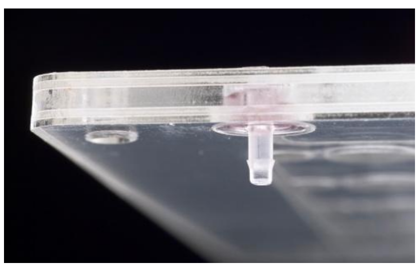
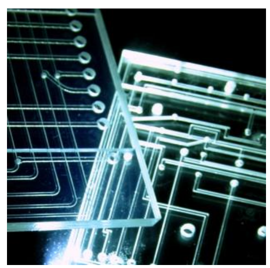
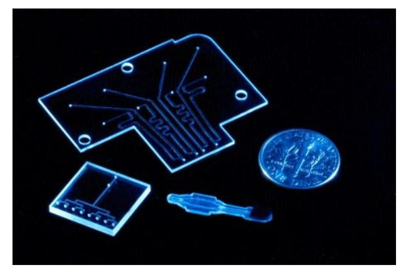
ALINE

Accelerated Microfluidic Development

Micro Engineered Lab on a Chip Solutions enabled through an Integrative Polymeric Platform




www.alineinc.com

TÜVRheinland®
ISO 9001:2008

ALine, Inc. • 19500 S. Rancho Way, Suite 107, Rancho Dominguez, CA 90220
t: 877-707-8575 f: 770.818.5475 w: www.alineinc.com

Medical Design Excellence Awards® Supplier to a 2009 Winner

Our Focus

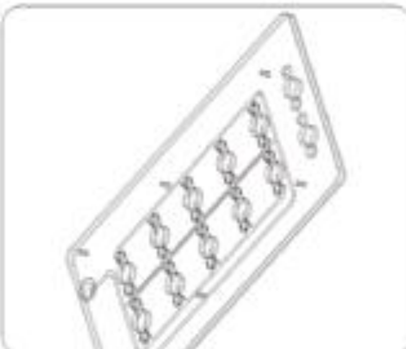
- Translate R&D to Commercialization for Microfluidics-based Products
- Provide all functional elements needed for Lab-on-a-Chip devices.
- Integrate functions with minimal complexity

ALine, Inc. • 19500 S. Rancho Way, Suite 107, Rancho Dominguez, CA 90220
t: 877-707-8575 f: 770.818.5475 w: www.alineinc.com

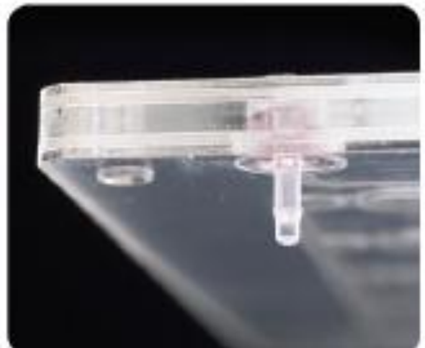
Commercially Relevant

- Easy to relate functional performance to simple, measurable characteristics of the device as made
- Adequate, reproducible performance over a wide range of conditions.
- Functional performance tolerant of other changes in the system (temp., pressure, fluid composition)

Integrative Polymeric Platform



3D Layered CAD design
- Split design into layers. export as dxf.
- Modular valve and vent
- Specify materials and thickness



Laser Machined Layers
- Channel width 125um
- Features density to within 0.75 mm
- Layer thickness from 12.5 microns to 3 mm

Align, Stack & Bond
- Pressure sensitive or thermal bond adhesives
- Pick & Place membrane
- .075 (.003") stack tolerance

Advantages of IPP

- Easy to prototype and rapidly test new designs/materials.
- Easy to measure effect of stack tolerances on performance.
- Easy to incorporate a variety of materials.
- Easy to assemble to other components.
- Path to volume can be achieved because tolerances can be well understood at the prototype scale. (Design Rules)

Electro-Mechanical Control

- Control the fluidics through external actuation.
- Functional performance not as tightly coupled to intrinsic material properties.
- Easier to control and engineer repeatable performance through a change in the instrument.
- Reduces the complexity and hence the cost of the disposable.

ALine, Inc. • 19500 S. Rancho Way, Suite 107, Rancho Dominguez, CA 90220
t: 877-707-8575 f: 770.818.5475 w: www.alineinc.com

Materials

SHEET and FILM Stock:

PMMA	.001” to .080”; 50 microns to 2 mm
PET	.0005” to .010”; 12.5 to 250 microns
POLYCARBONATE	.005” and .010” ; 125 and 250 microns
POLYSTYRENE	.002” to .005”; 50 to 125 microns
POLYPROPYLENE	.002” to .040”; 50 to 1 mm
COP/COC	.002” and .007”; 50 and 175 microns
SILICONE	.005” to .060”; 125 microns to 1.5 mm
POLYIMIDE	.001” to .003”; 25 to 75 microns
FEP, PTFE, PVDF	.001” to .010”; 25 to 250 microns

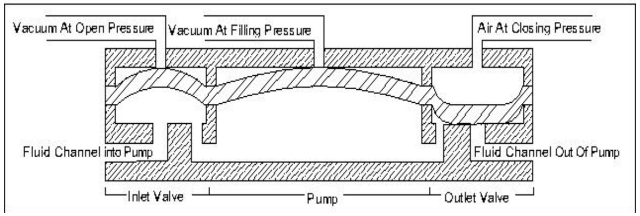
Adhesives: 50 micron silicone (PCR compatible), 25 micron acrylic, 25 micron olefinic thermal bond adhesives (range of temps up to 150C), direct thermal bonding

Membrane materials: nylon, polypropylene, PES, PS

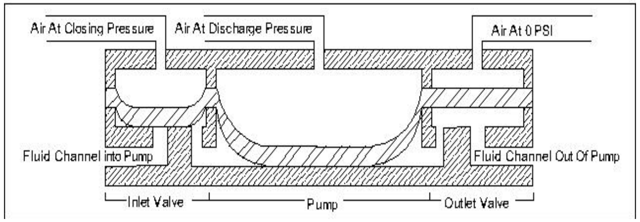
Accelerated Microfluidic Development

Functionality

On –Board Pumps



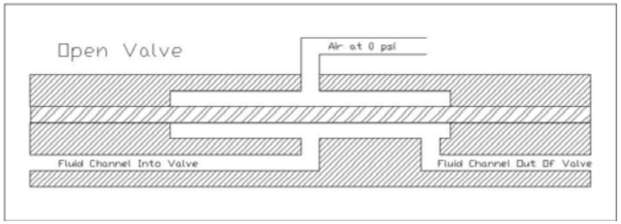
Filling pump.



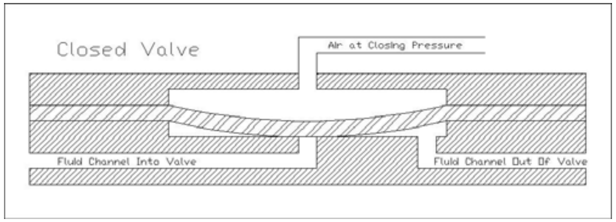
Discharging pump.

http://www.alineinc.com/pdf/Modular_Designs_for_Reproducible_Performance_of_On-Board_Pumps.pdf

On –Board Valves



Diaphragm valve open



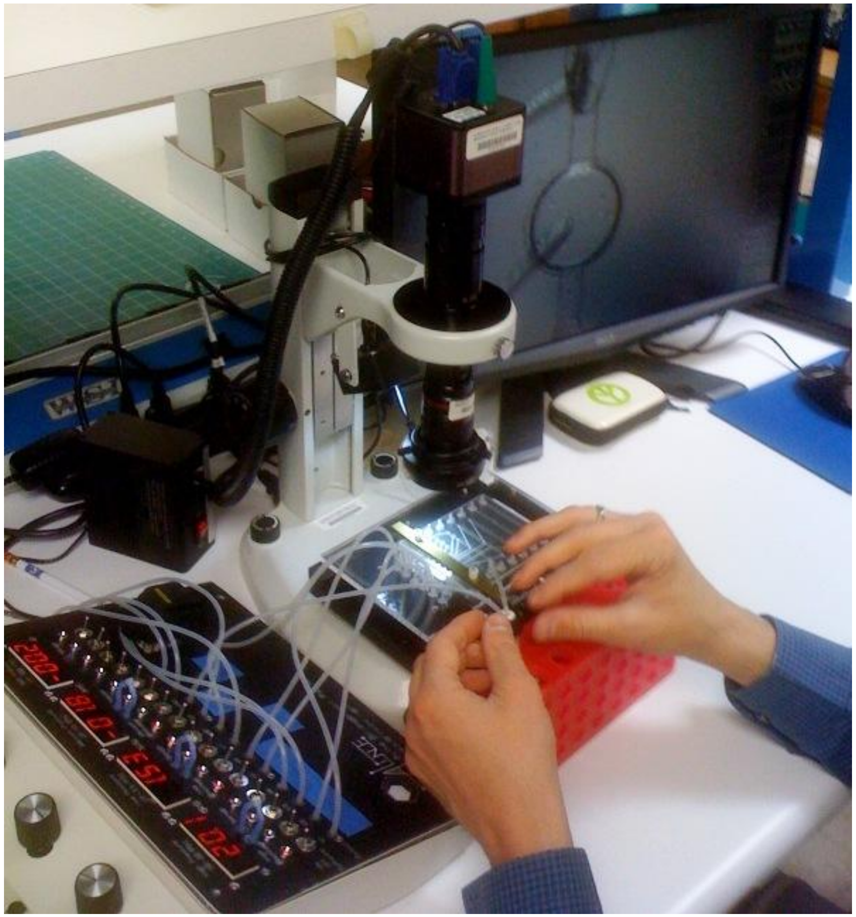
Diaphragm valve closed

http://www.alineinc.com/pdf/On_board_pneumatic_valves_ALine_Inc..pdf

Design Rules

- Feature sizes: 0.125 mm channels, 5% width variability; 0.250 mm holes (vias)
- Feature density: 1 mm between edge to edge, 0.5 mm in some cases
- Channels: 0.025mm to 1.5 mm tall, typical: .125 mm tall x .300 mm wide, channel edges contain adhesive; minimizes exposure.
- Valves: 2.0 mm x 3.0 mm
- Pumps: > 2mm dia. x > .250 mm deep to get 2% var. in pump volume.
- Macro porous membranes: pick and place
- Interface to glass, PCBs, silicon, flex circuits, packaged sensors, Au on glass/plastic.
- Modular add on components: PCR chambers, filtration assemblies, septums, one way valves.

ADEPT Developers Kit



- 4 to 32 valve system with up to 2 dispense pumps,
- Pressure sensors,
- High pressure, low pressure, vacuum,
- Manual or computer control with interface to LabView,
- SD card slot for text-based programs, .
- x-y custom manifold platform,
- USB camera or Optical Comparator interface
- Hose barb, or leuer connections to bridge the instrument to the manifold.
- Useful for developing fluidic control routines as well as for QC of fluidic cards.

Modular Design

Subassembly 1: Interface: reservoirs, blister packs, waste; injection molded.

Subassembly 2: Functional components: valves, vents, pumps.

Subassembly 3: Channels; interface to the sensor; either optical and electrochemical.

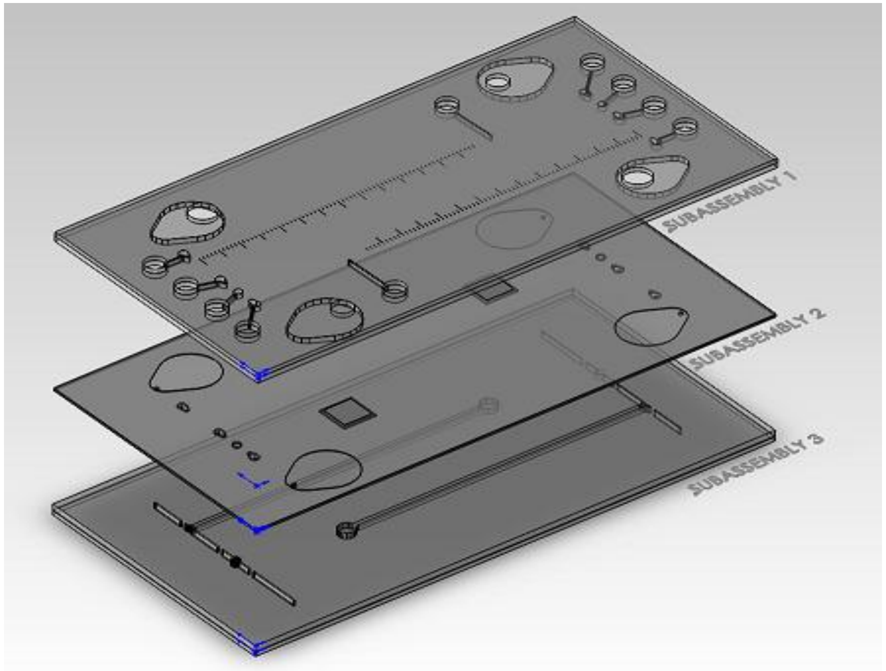
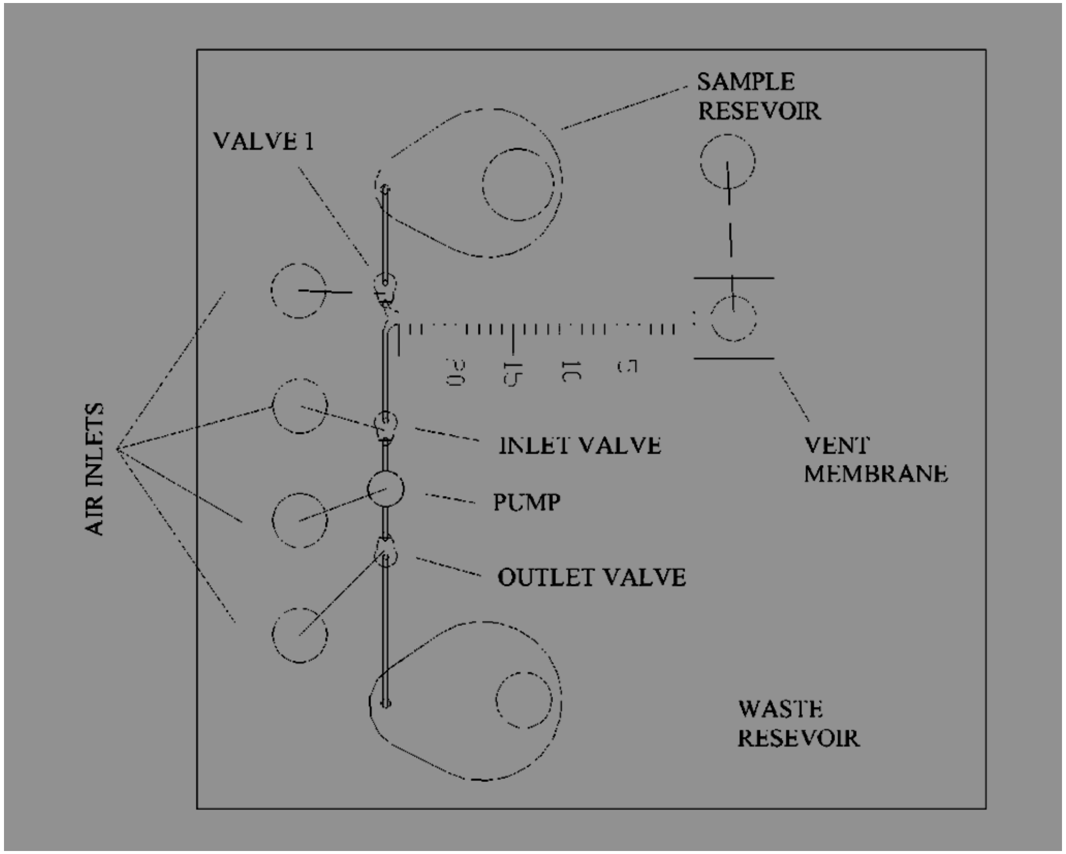


***Figure 1**: Exploded View of Test Device; subassembly one contains the reservoirs and pneumatic connections to the manifold, Subassembly 2 contains the vent membrane the valve actuation components, Subassembly 3 contains the channels.*

Functional Performance

Test Card with Valves and Pumps



Inter- Device

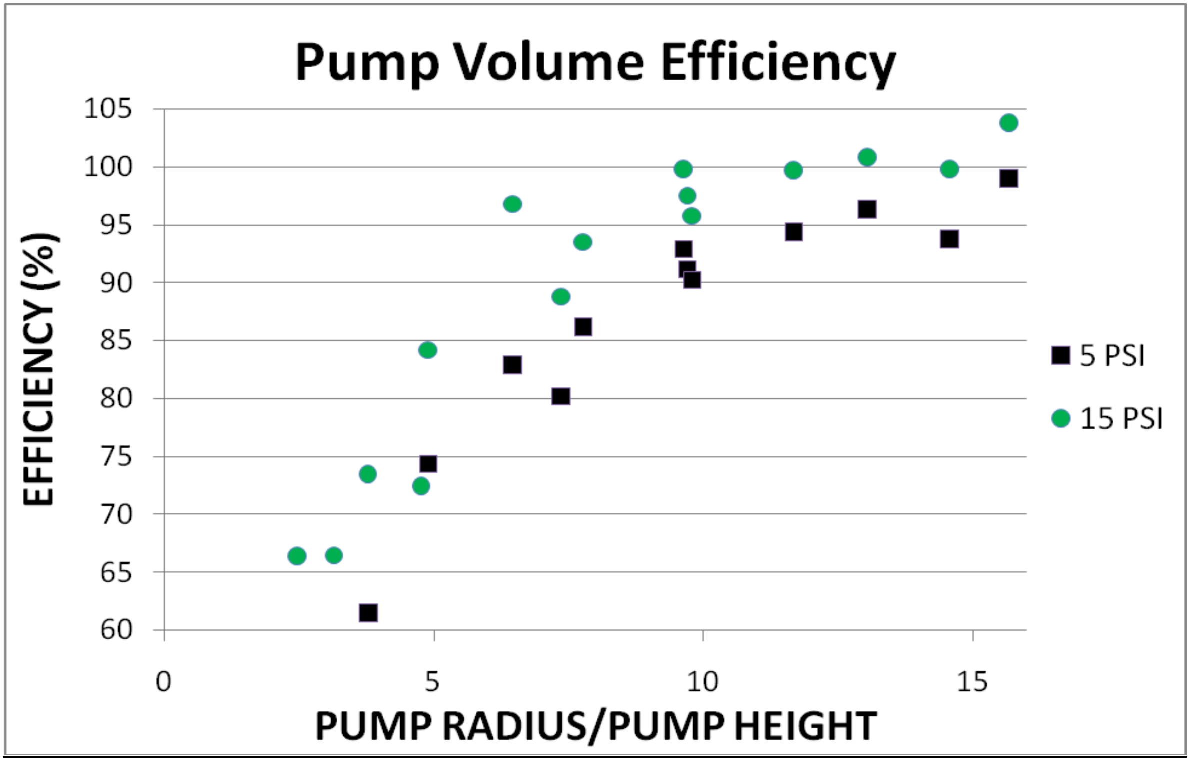
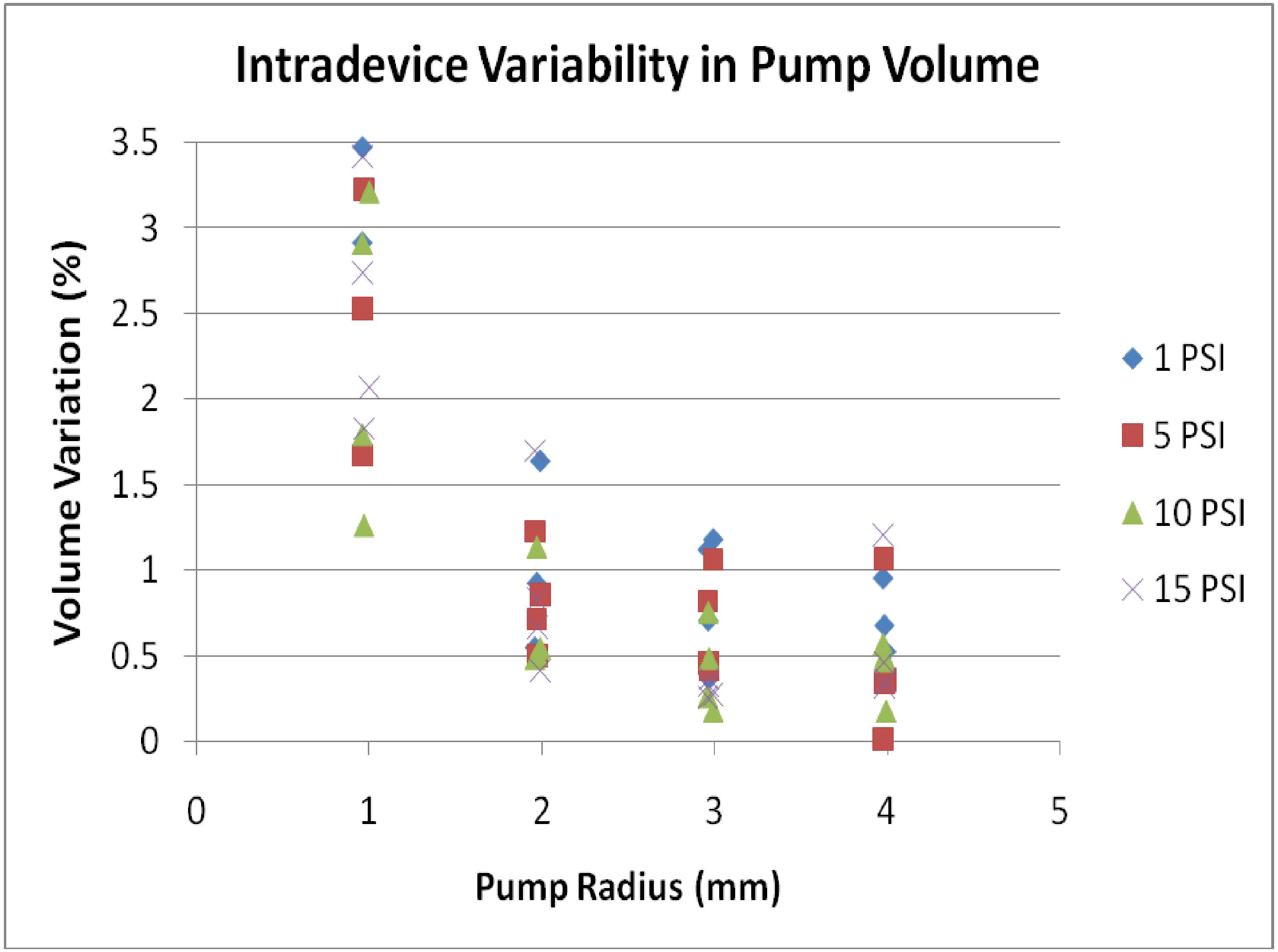


Table 2: Summary of Interdevice Variation				
Radius	1 mm	2 mm	3 mm	4 mm
Avg. Volume Pumped (uL)	0.75	4.10	9.16	16.65
Standard Deviation (uL)	0.05	0.19	0.41	0.34
Percent Variation	6.47	4.71	4.50	2.05


Intradevice Variability in Pump Volume
Volume Variation (%)
3.5
3
2.5
2
1.5
1
0.5
0
0
1
2
3
4
5
Pump Radius (mm)
1 PSI
5 PSI
10 PSI
15 PSI

Subassembly 1: Injection molded sample interface reservoir component

Subassembly 2: Laminate channel component containing valves, vents, pumps and channels

Subassembly 3: Detection component (PCB, optical, or flex circuit)

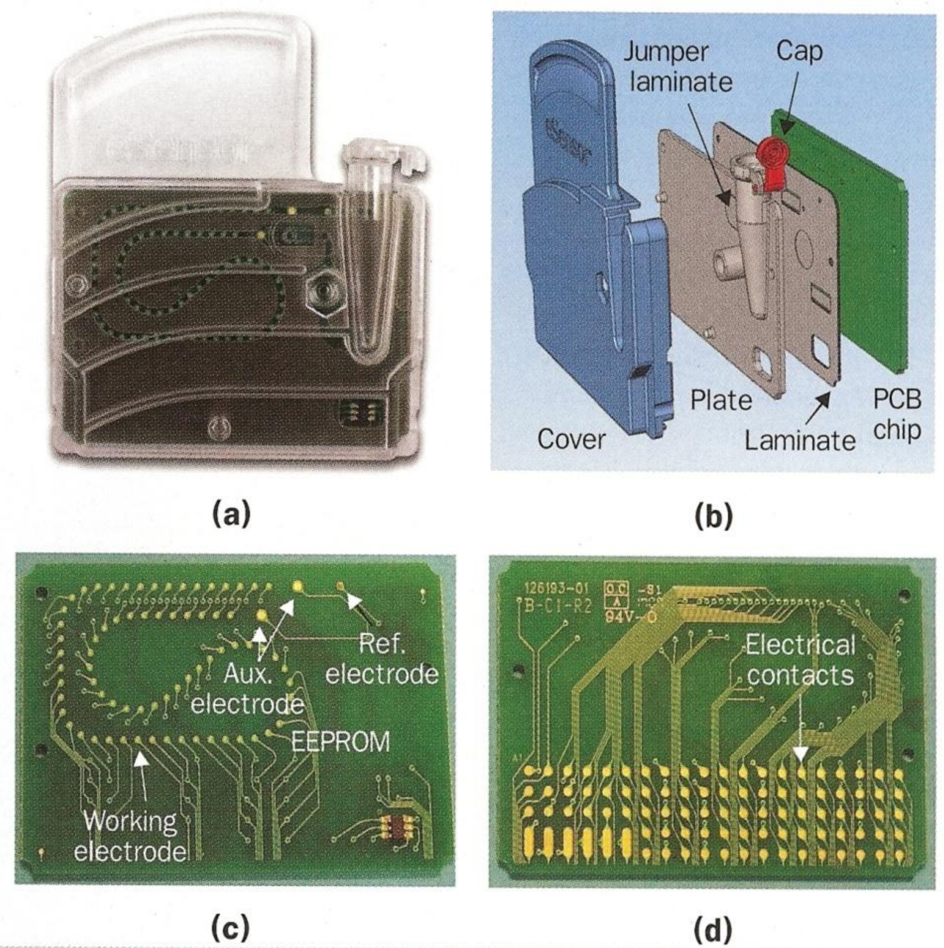


Figure 5. (a) Photograph of an eSensor cartridge. (b) Exploded schematic view of the cartridge components. Photographs of the PCB chip that measures 56 x 39 mm: (c) front (electrode pad) view; (d) back (connector pad) view.

Manufacturing Methods

1MM parts/yr = 1 part every six seconds (85k parts/month)

	Mass or Flow Manufacturing	Batch or Flexible manufacturing
Method	Flow of material is linear through the process, equipment fixed, and produces one product	Material moves through each type of operation in a group, equipment is adaptable to different products
Flexibility	None - every piece of equipment linked together for production of a single product	Some - equipment is modular and mobile to maximize work flow efficiency
Capital Investment	High Capital Investment + High NRE	Low Capital Investment + Low NRE
>1 MM/yr <1 MM/yr	\$ \$\$\$\$	\$\$ \$\$

ALine, Inc. • 19500 S. Rancho Way, Suite 107, Rancho Dominguez, CA 90220
t: 877-707-8575 f: 770.818.5475 w: www.alineinc.com

Roadmap for Scale-up

Roadmap for Scale-up of a Proof of Concept Design				
Volume	1,000	10,000	100,000	1,000,000
Process	Manual PLT	Automated PLT	Fully Automated PLT + Optimized Design	Roll to Roll+ Optimized Design
Device: 7 layer design with mixed materials, on-board valves, vents, Pop on Subassemblies	pin fixtures, manual cleaning and assembly	Gantry laser, automated lamination, current design	Further improvements in channel formation method, and processing	Dedicated mfg. line, reduced material costs, simplified design
Per Piece Price Estimate	$22.00	$12.00	$5.00	$1.50

ALine, Inc. • 19500 S. Rancho Way, Suite 107, Rancho Dominguez, CA 90220
t: 877-707-8575 f: 770.818.5475 w: www.alineinc.com