

Recent Developments in Microfluidic Commercialization

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enablingMNT

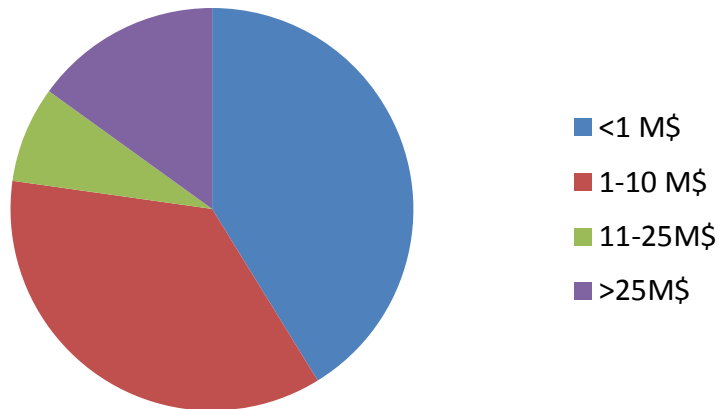
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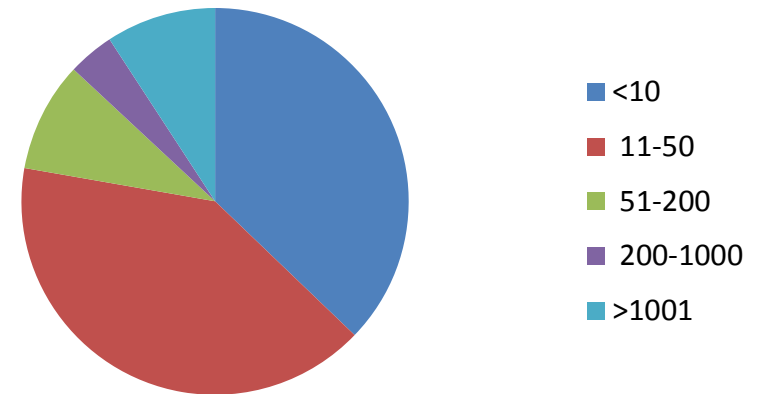
- The **enablingMNT** group provides support to new and established businesses in the Micro & Nano Technology (MNT) and System Integration sectors where the uptake of MNT offers enhanced performance and potential market advantage.
- Its partners each have over 20 years of experience in business development, marketing, and technology related services delivered to both private and public sector customers.
- The group have maintained a leading position in the field through strong participation in European projects in the MNT and System Integration areas and collaboration with international support organisations including MEMS Industry Group, NEXUS, MANCEF, IVAM, etc.

The microfluidic industry

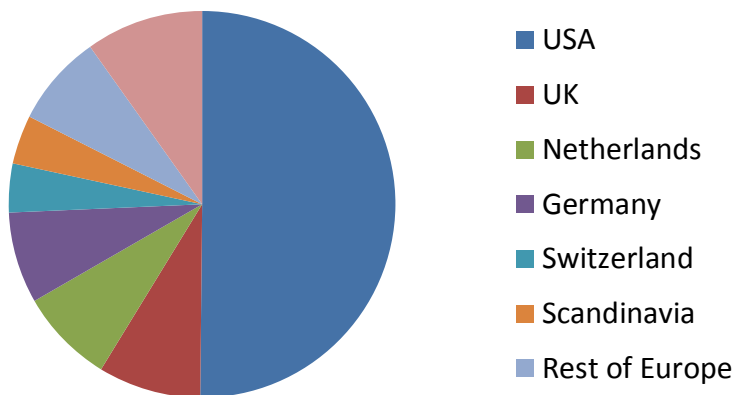
Investment in the companies



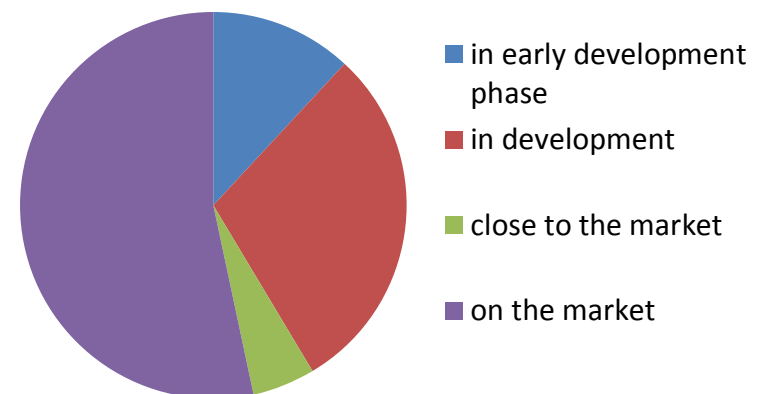
Size of the companies



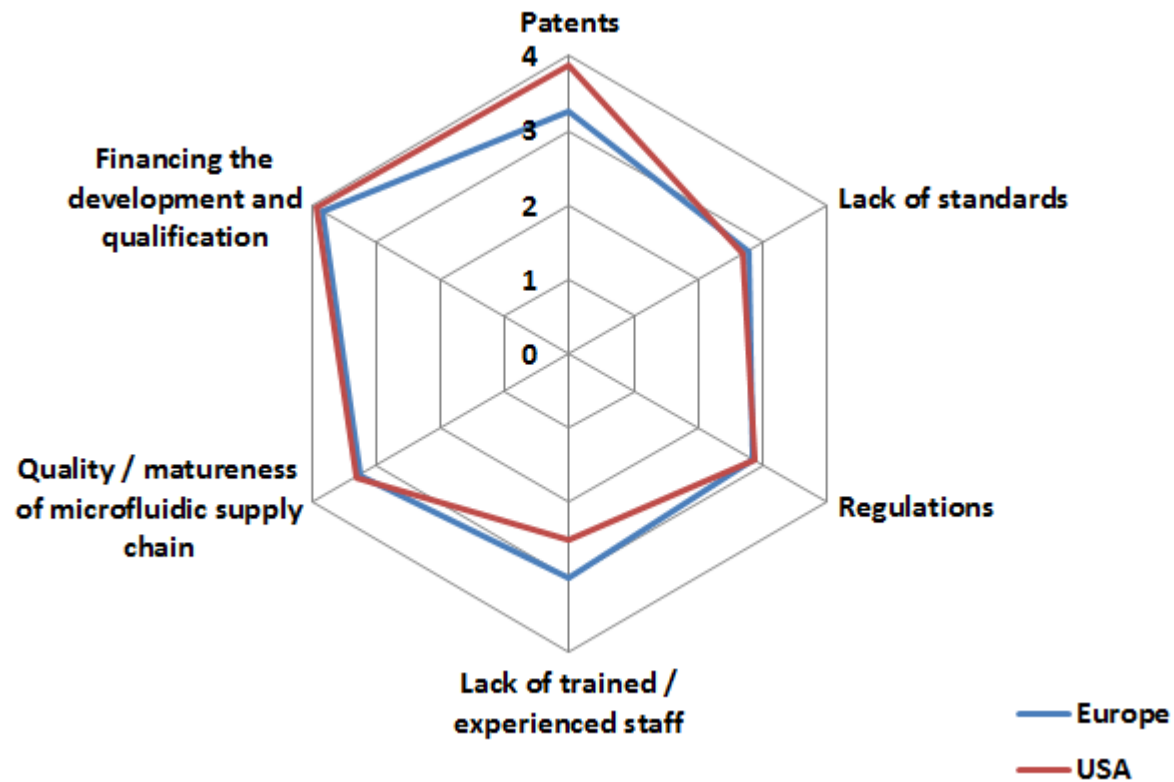
Microfluidic companies



Company status



Biggest challenges facing the microfluidic industry



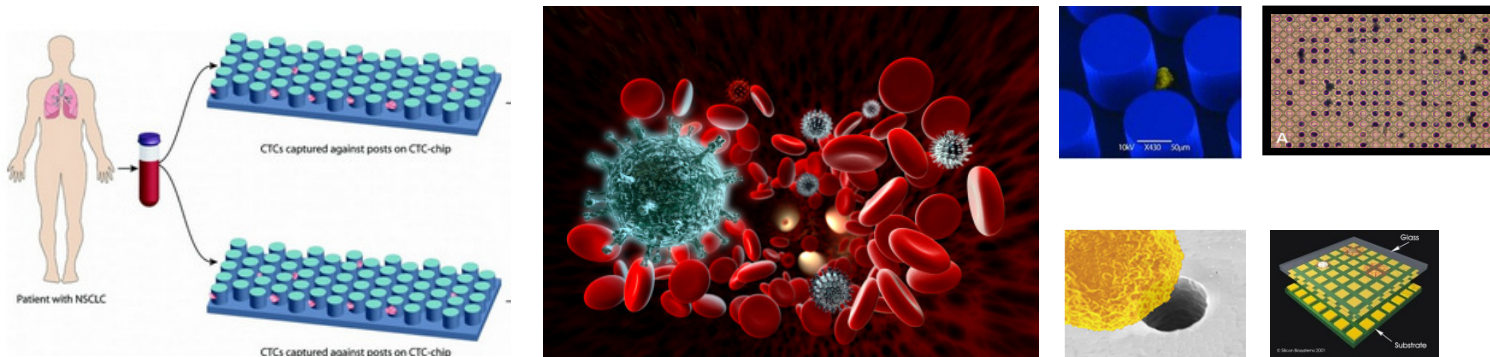
Development priorities per segment:

- Processing industry: integration of microfluidic components
- Analytical equipment suppliers: component development + design and modeling
- Supply chain: test & measurement
- Research community: application development
- **ALL: RELIABILITY**

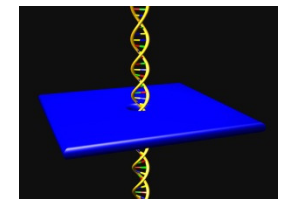


Hits / hot or hype?

- Circulating Tumor Cells (CTC's): The ability to capture and identify specific cells from blood, even when present in only small quantities, opens the possibility to diagnose cancer at a very early stage.

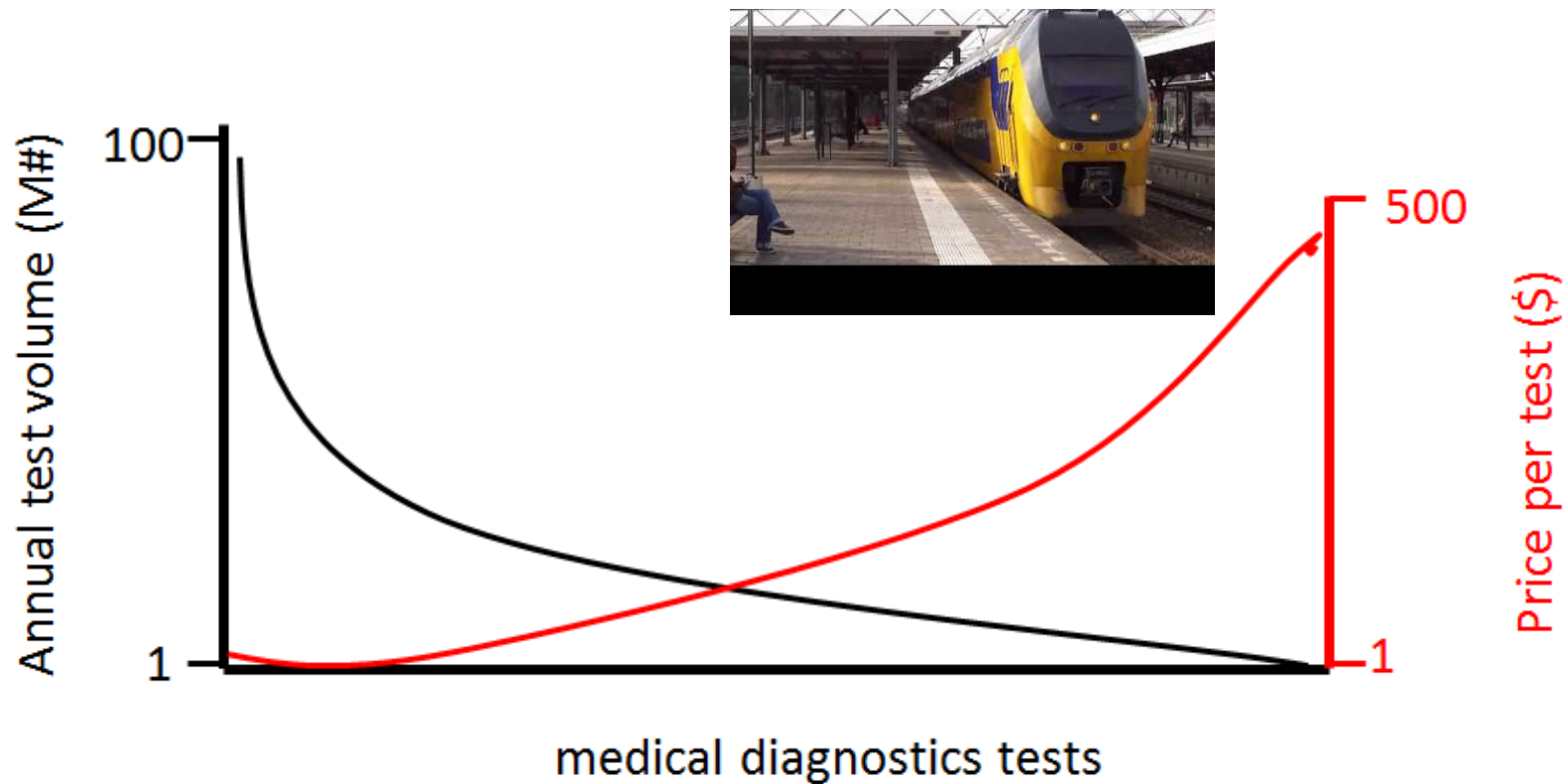


- DNA sequencing, one molecule at a time, no amplification?



Long tail market: Medical Diagnostics

PLATFORM TECHNOLOGY?



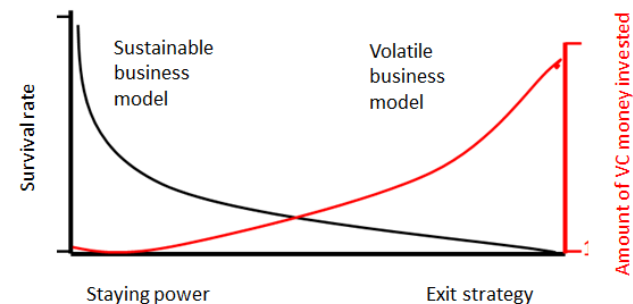
Business strategy

Organic growth

- [Formulatrix](#) (protein crystallization automation solutions) started in 2002 with 2 people; they managed to survive the first two years with services and introduced their first product during the second year. After 8 year they had 204 employees and an installed base of 237 pieces of equipment at 17 sites.

VC backed

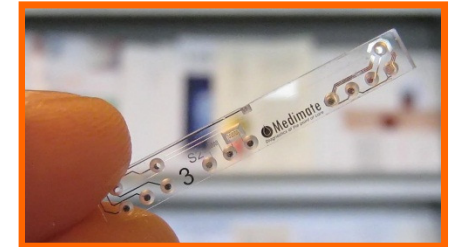
- [Oxford Nanopore](#) founded in 2005, secured over 100 M\$ for the direct, electronic analysis of single molecules. Intends to commercialize DNA strand sequencing products, directly to customers within 2012.



Not always a straightforward business case

- There are about 10 high volume diagnostic opportunities, like for instance diabetes, TB, HIV, etc., but also hundreds of tests where the volumes are less, often substantial less than 1 million tests per year.
- Several chronic diseases, the (sometimes costly) measurement can show a substantial added value in another part of the health care chain.
- Tools like implantable pumps or microneedles reduce side effects / optimize the working of a drug (and extend the patent protection period). But they are also making the microfluidic instrument part of the drug sales. Those coupled sales will result in an intertwining of markets and companies.

Examples of complex business cases



- Medspray inhaler:
 - The big money is in the drug, the microfluidic component is an enabler.
 - Launching customer is paying the development bill; each device is developed in relation to a certain drug.

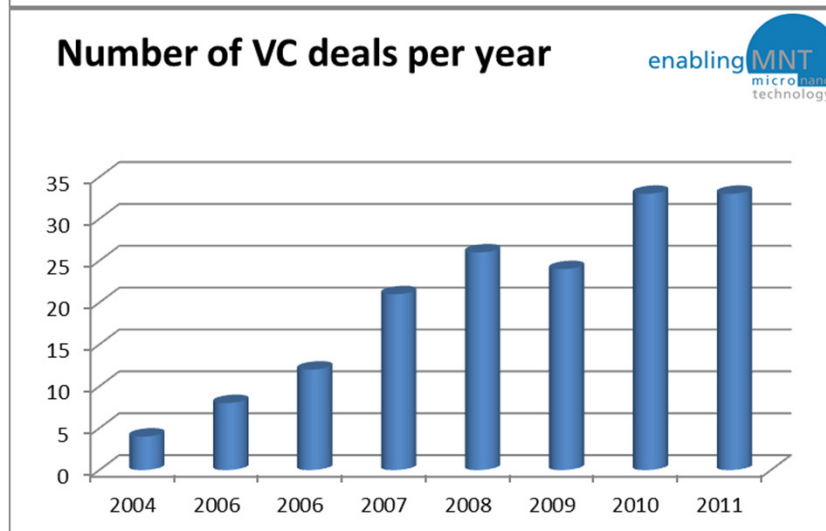
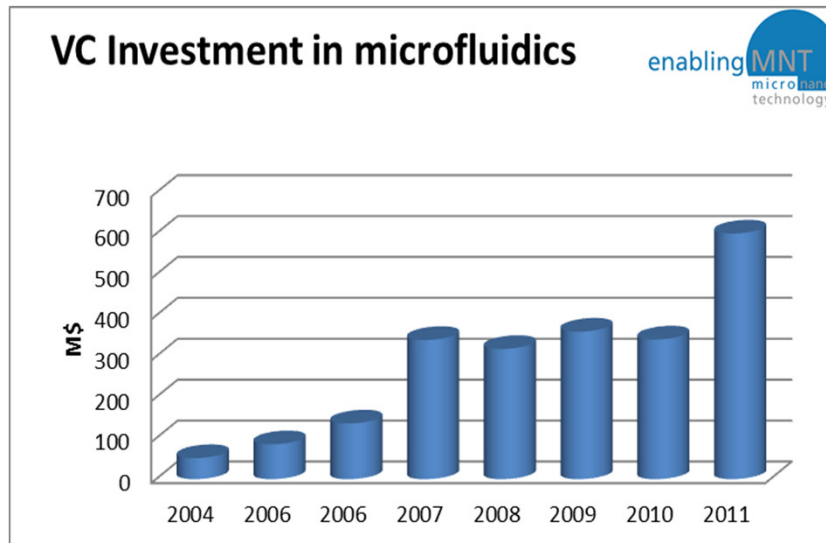


- Medimate:
 - Big saving is related to the patient's risk of side effects of the drugs
 - the insurance company benefit financially when the products becomes a success.
 - Guess who is investing in the company and who is launching customer?

University spin off hot spots (microfluidics)

- **Havard** (Claros, Vista Therapeutics, g nubio, DFA, Nano Terra)
- **MIT** (Bostonms, Firefly BioWorks, Netbio, Pharyx, Biosscale, Hepregen, Microchips)
- **University of California Berkeley** (Cellasic, Nanomix, IntegenX)
- **University of California San Diego** (Celula, Nanosort, Biological Dynamics)
- **University of Texas** (Resonant Sensors, Nanomedical systems, Leonardo Biosystems)
- **Cornell University** (HμREL, Pacific Biosciences, Advion)
- **Caltech** (Labsmith, LeukoDx, Fluidigm)
- **EPFL** (Spinomix, Diagnoswiss, Biocartis, Ayanda, Abionic)
- **Imperial College London** (DNAE, Microsaic, Molecular Vision, Deltadot)
- **Cambridge University** (Cambridge Biomagnetics, Sphere Fluidics)
- **A*STAR / National University of Singapore** (Micropoint Technologies, Veredus, Cellsievo, Curiox, Clearbridge, CE Resource)
- **IMM** (Ehrfeld, Mikroglas, ThinXXS)
- **University Twente** (U-needle, Aquamarijn, Ibis Technologies, Kryoz, Medimate, mylife technologies, Medimate, Ostendum, Opisense, Senzair)

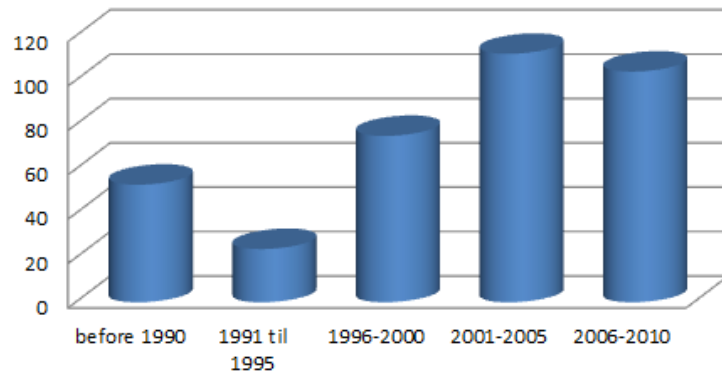
Investments & acquisitions



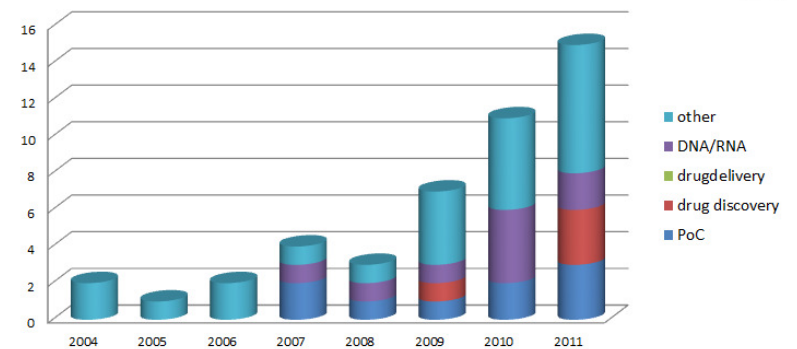
- **Abott** (i-Stat, IBIS)
- **Agilent** (Biotrove, lab901, Biocos)
- **Beckman Coulter** (Advalytix, Blue Ocean Biomedical)
- **Inverness Medical Innovations** (Biosite, Epocal)
- **Johnson & Johnson** (Veridex, Amic)
- **Life Technologies** (Cytonix, StokeBio, Ion Torrent, Biotrove)
- **Pall** (Genesystems, MicroReactor Technologies)
- **Roche** (454, Biomicrosystems, Medingo)
- **Sony** (iCyt, Miconic)
- **PerkinElmer** (Caliper, Evotec Technologies)
- **Bio-Rad** (Quantalife, Digital PCR Technology)
- **Becton & Dickinson** (Handlylab)
- Etc.

Happy ending for university spin offs?

Launch of the company



Number of Microfluidic Takeovers per year



Survival of the fittest

R&D project	200
Start up company	10
Some funding	9
Acquired	8
Market introduction	5
“Big” market success	1-2?

Survival rate

Staying power needed:

- Time to “success”: average 9 years
- Time to failure: average 7 years
- Time to market: average >10 years

Are we getting closer to the market with microfluidics?



	R&D	Pre-development	Development trials	Entering the market	On the market
<i>Patchclamp</i>					R&D
<i>Micro dispensing</i>			High volume electronics		Medical diagnostics
<i>Lab on chip</i>				Medical diagnostics	
<i>MS and LC instruments</i>				Industrial, R&D	
<i>Sample preparation devices</i>				Medical diagnostics, R&D	
<i>Array with flow control and /or electronics integrated</i>				Medical diagnostics	
<i>Electronic coolers</i>		Sensors & Telecom		Electronics	
<i>Microreactors</i>			Chemical Industry		
<i>Emulsification</i>		Pharma			
<i>Drug development</i>			Pharma		
<i>Microneedle</i>		Drug delivery	Drug delivery		
<i>CE (stand alone)</i>			Medical/ veterinary		
<i>Artificial organs</i>	Medical				

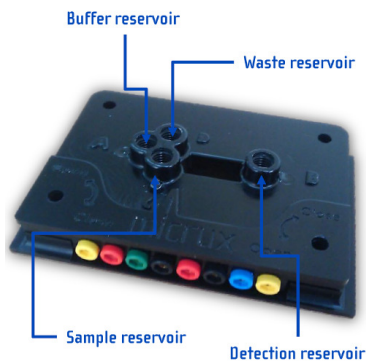
**STATUS
2009**

	R&D	Pre-development	Development trials	Entering the market	On the market
<i>Patchclamp</i>					R&D
<i>Micro dispensing</i>			High volume electronics		Medical diagnostics
<i>Lab on chip</i>				Medical diagnostics	
<i>MS and LC instruments</i>				Industrial, R&D	
<i>Sample preparation devices</i>				Medical diagnostics	R&D
<i>Array with flow control and /or electronics integrated</i>				Medical diagnostics	R&D
<i>Electronic coolers</i>			Sensors & Telecom	Electronics	
<i>Microreactors</i>				Chemical Industry	
<i>Emulsification</i>		Pharma			
<i>Drug development</i>			Pharma		
<i>Microneedle</i>		Drug delivery	Drug delivery		
<i>CE (stand alone)</i>				Medical/ veterinary	
<i>Artificial organs</i>	Medical				

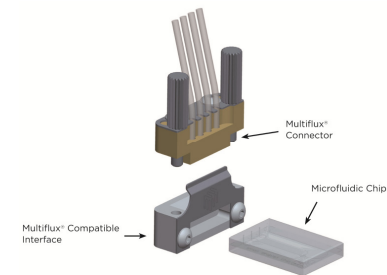
STATUS
2012

Examples of new products and products coming soon (1)

- Industrial equipment:
 - Sono-Tek ultrasonic coating device,
 - Cetoni & Corning microreactors,
 - Microfluidic interconnects by Dolomite,
 - Micrux chipholder and the “plug and play” chipholder from Micronit ,
 - Advanced MicroLabs: online process analyzer based on CE.



6/27/2012



Examples of new products and products coming soon (2)

- Point of Care
 - Epocal FDA clearance for its Point of Care Lactate test, now being sold by Alere
 - Lingvita: low cost generic diagnostic test platform, launched 2011
 - Samsung 19 different blood tests in just 12 minutes
 - Medimate hopes to also see commercial turnover in 2012 with its lithium home test for patients suffering from Bipolar Disorder.
 - Microvisk is gearing up for market introduction in 2012 with its device to monitor the blood clotting.



Standards, or no standards?

- The general answer can be best described as “perhaps”.
- The likelihood is rated highest for suppliers of analytical instruments and chemical reactors followed, surprisingly, by PoC instrumentation.
- But opinions are divided: over 25% will not participate in any standard discussion.



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Barriers & Drivers for standards in microfluidics

Barriers:

- Market position of the companies (that are dominant in the market or are expecting to achieve such dominance).
- Investment in current products might become worthless.
- Diversity in the existing products already on the market.
- Lack of uniformity in our vocabulary.
- Existing standards in established industries.

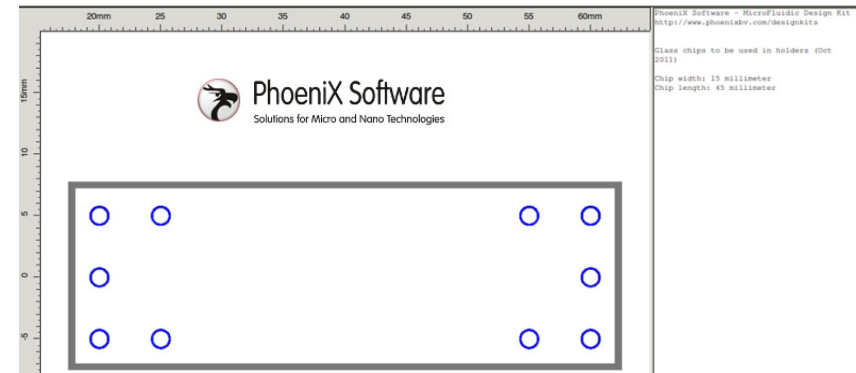
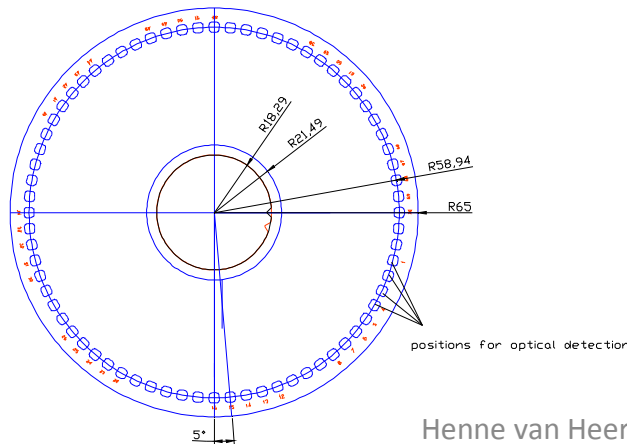
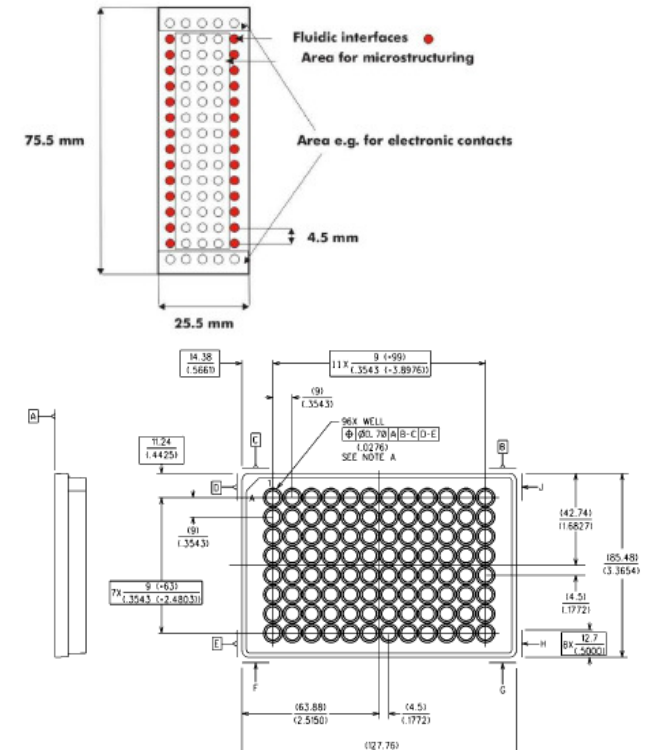
Drivers:

- Health care: to enable diversity in testing, there are hundreds of specific tests needed, with a limited number of instruments
- Analytical instruments / processing equipment: to enable the selection of the best components and the ability to compare / qualify those components and the systems.



Pro/forma microfluidic standards

- Microscope slide
- Microtiterplate:
- 45*15 mm glass chip
- Optical disk



Ongoing standard discussions:

- Semi: proposal for multi port interconnect in discussion. (8 parallel fluidic tubes with a center to center spacing of 0.500 mm and an ID of 0.250 mm)
 - SEMI Draft Document 4691, New standard: specification for high density permanent connections between microfluidic devices
 - SEMI MS7-0708 - Specification for Microfluidic Interfaces to Electronic Device Packages
 - SEMI MS6-0308 - Guide for design and materials for interfacing microfluidic Systems
- Nessi: mainly about sampling for process control.
 - ISA-SP76, Composition Analyzers?
- DIN standardization group on microreaction technology: Also working on characterization processes for microreactors.
 - ISO 10991 Micro process engineering - vocabulary
- MF3 (Microfluidics Consortium): multi port interconnects.

General observations

- The products are there, but are not reliable enough, too expensive and the quality of the components is not good enough. Giving more attention to standards might help.
- The community worries very much about how to finance the development and how to survive the IP situation.
- We see signs of maturity
 - Consolidations
 - License deals
 - Better formulated business proposals
 - Standard discussions
 - Availability of training / easy to use tools etc.
 - Microfluidic Industry Consortia: MinacNed, FMMC, MF3



Your chance to meet us all:

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MicroNano
CONFERENCE '12

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10 - 11 DECEMBER 2012

De ReeHorst, Ede
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