Selfmonitoring by POCT

Trends

Robbert J. Slingerland
(r.j.slingerland@isala.nl)

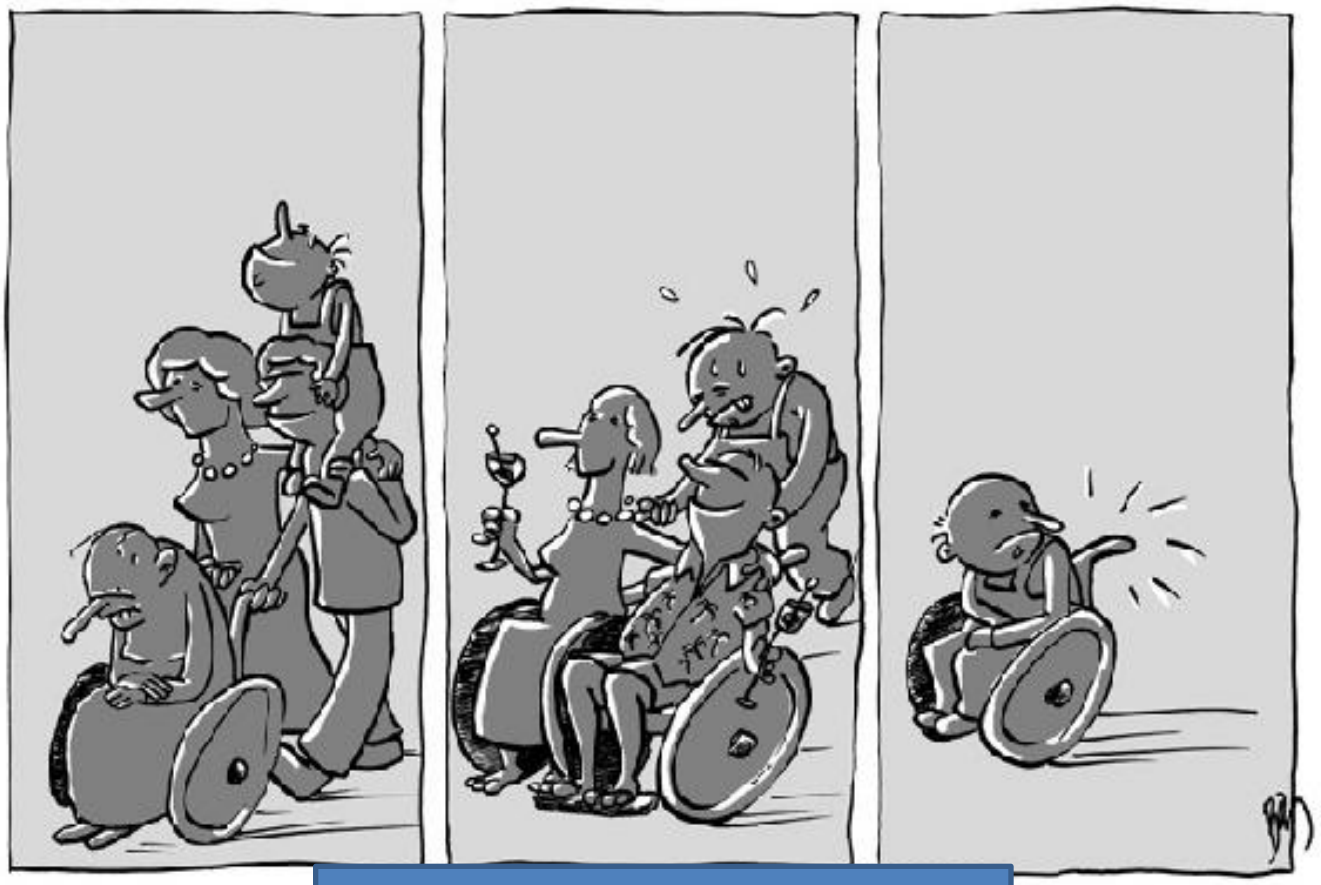
Disclosure of Potential Conflicts of Interest

- *Employment or Leadership: none declared*
- *Consultant or Advisory Roles: many companies (but unpaid); none declared*
- *Stock Ownership: none declared*
- *Research Funding: none declared*
- *Honoraria: none declared*
- *Expert Testimony: none declared*

Content

- Changes Health Care
- Quality Home-use Instruments
- Harmonised Values Health Care Chain
- Performance of Glucose Meters in Patients Hands
- Changes in Diagnostics (Multi-disease/Non-invasive/translating data/Smaller)

Certainties



Demography

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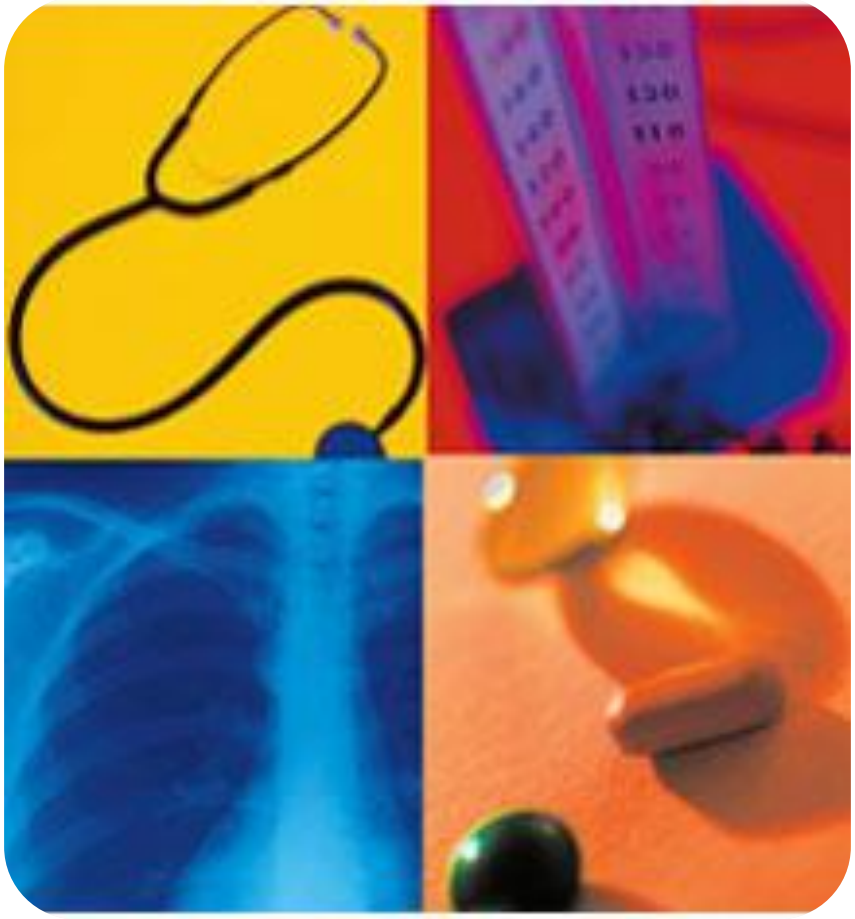
Uncertainties

Who pushes health-care changes?

Professional or patient?



Uncertainties

How do we think about health care in the future?

Is health care only a cost or provides it also benefits to society?

Uncertainties and tensions

Patiënt empowerment or professional in charge

Care is a cost or an investment with benefits for society

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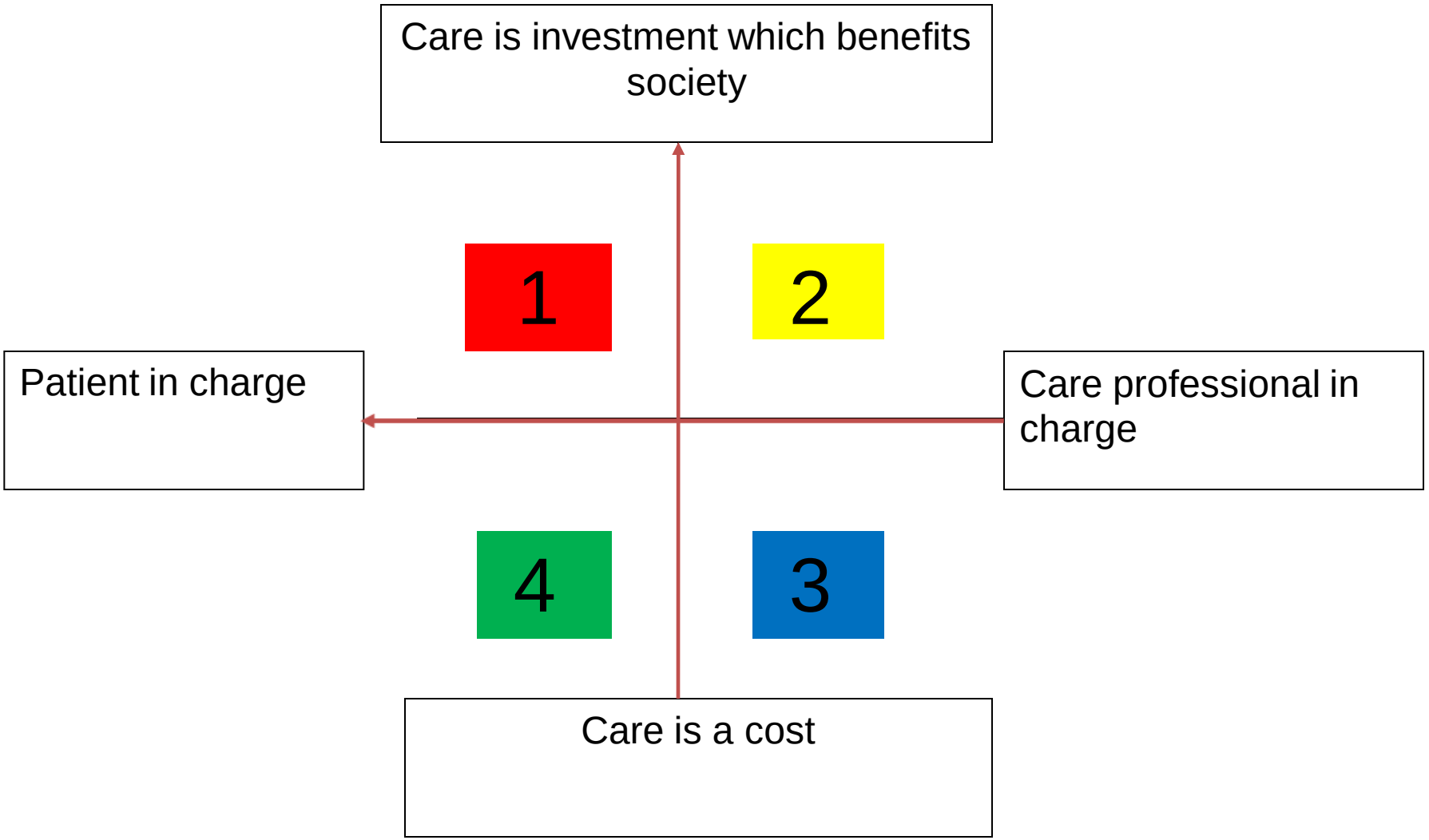
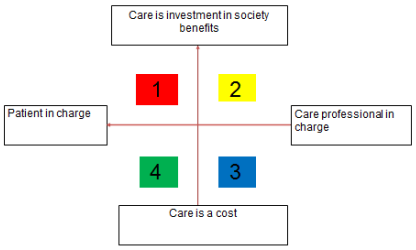
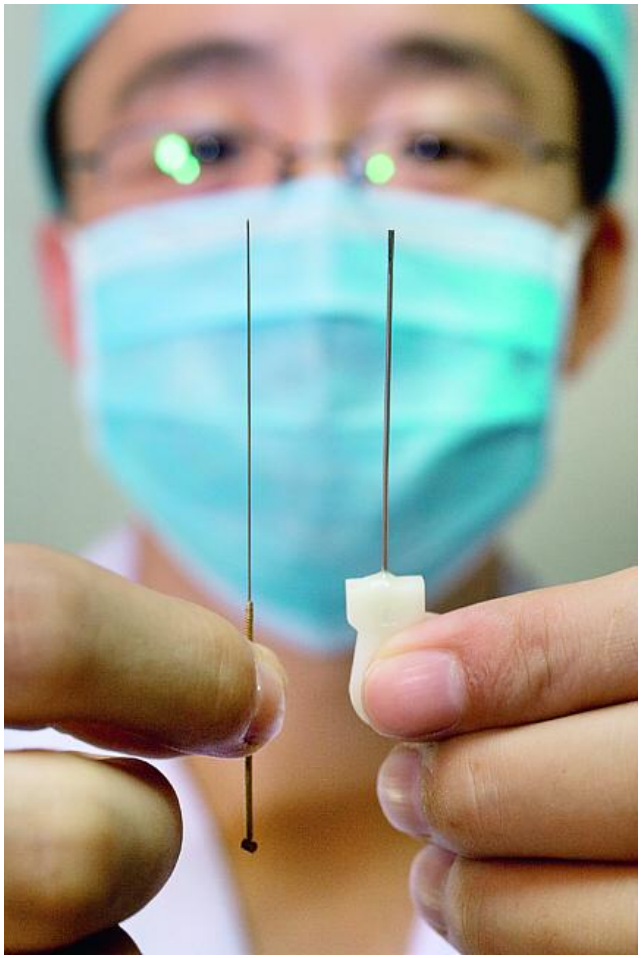

Care is investment which benefits society
1
2
Patient in charge
Care professional in charge
4
3
Care is a cost

Kind of blue



- Care will be limited to medical and nurse services (POCT)
- Limit pull by patients; limit access for new patients (POCT)
- Focus professional handling: medical evidence based at minimum quality standard (POCT)



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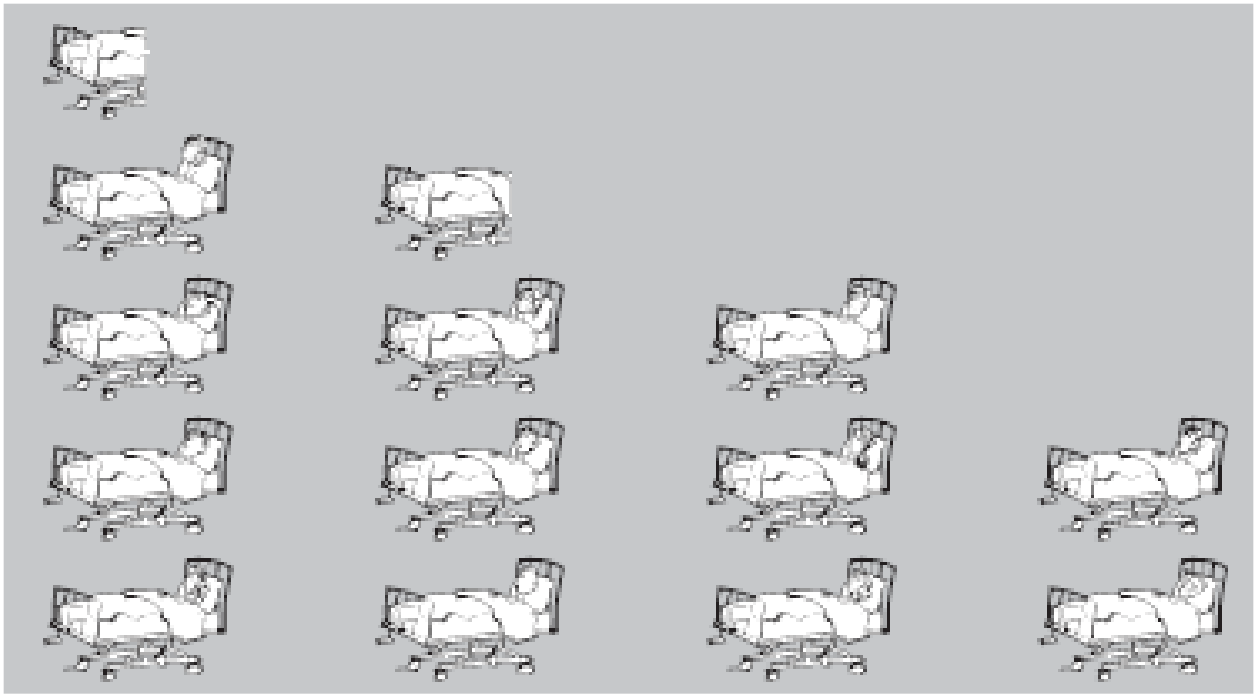
To reduce cost of healthcare



Future

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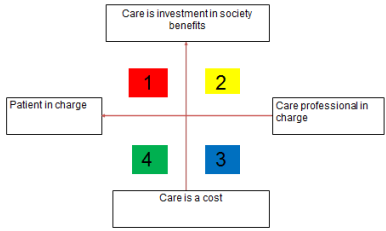
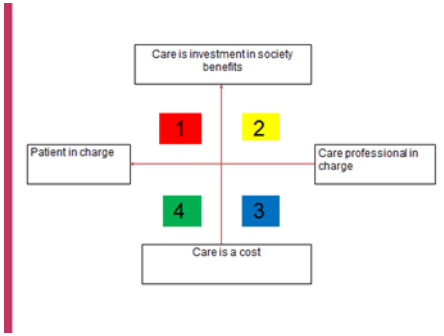
In the yellow pages



- Professionals care services:high patient health benefit / quick commencement of labor
  POCT/Home-use testing
- Focus handlings: preventing relaps and permanent malfunction in other life domains
  Home-use testing

Get ready for red



- Patients search services for quality of live (balancing work, education, family live, participation in society) Home-use testing
- Focus professional: fast access and services to other sectors
- Innovations: support healthy and unhealty citizens in participation in society 24/7, health and behaviour Home-use testing

POCT to improve quality of live

	Traditional	*POCT*
Analysis:	> 1 hour	few minutes
Where:	Hospital	Home
Hardware:	Complex	KISS
User:	Highly educated	Patient
Sample:	Tube of blood (Serum)	1 droplet of blood
Patient Empowerment:	No	Yes

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Evergreens

- Care limited to medical and nurse services (POCT)
- Focus professional: maximize therapy adherence (POCT/Home-use testing)
- Cut back overhead costs and costs of care providers. More patiënts served for less costs (POCT/Home-use testing)

POCT/home-use Testing

POCT (Cost /Professional)

- Diabetes (glucose /HbA1c)
- MI (troponins)
- Heart failure (pro)BNP
- Kidney function (creatinin)
- Bipolar disorders: monitoring toxicity (Lithium)
- Anti-coag monitoring (INR, D-dimer)
- Hypertension (Salt balance)
- Other diagnostics (total cholesterol, HDL-chol etc.)

Home-use Testing (Patient /Wellness !)

- Diabetes
- Heart failure monitoring
- Kidney monitoring (creatinin)
- Anti-coag monitoring (INR)
- Hypertension (Salt balance)
- Other compendium diagnostics (total cholesterol, HDL-chol etc.)

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A Step Closer
There is only so much one can see.
Discover more from a different point of view

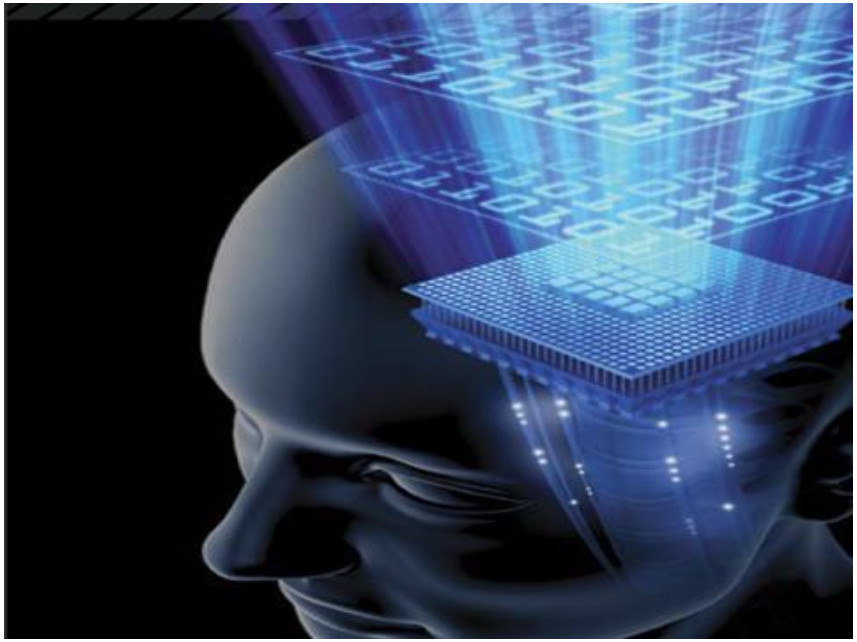
What Quality is needed?
Total allowable Error: example glucose

- For glucose the within-person CVw is 5.7%
- The between-person variation CVb is 6.9%.
- From these the Allowable Bias is calculated as

  $AB = 0.25*\sqrt{(CVw^2 + CVb^2)} = 2.23\%$.
- The desirable analytical variation

  $CVd = 0.5*CVw = 2.9\%$
- The Total Allowable Error

  $TAE = AB + (1.65 * CVd) =$ **7.0%**

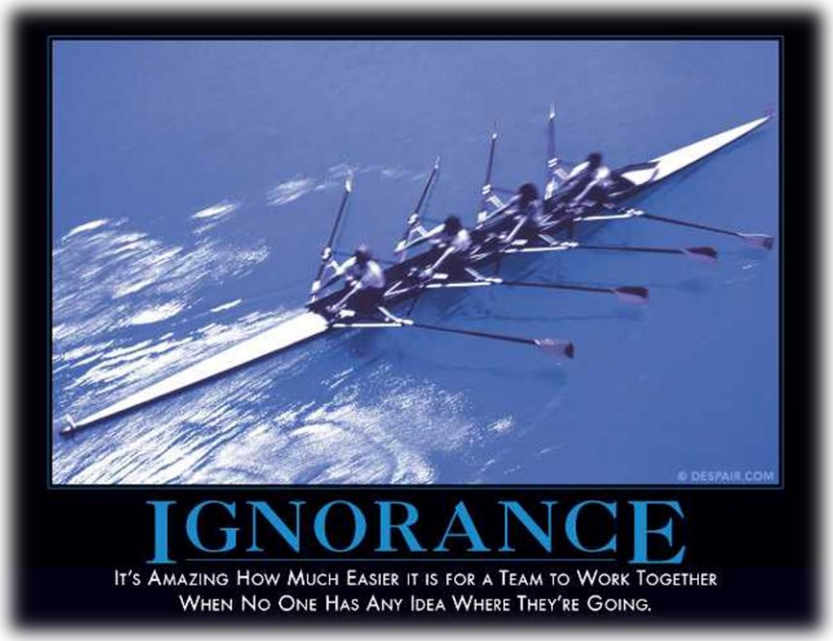


Jansen and Slingerland, Clin Chem Lab Med 2010; 48(7): 1021-1027

What Quality is needed?
Total allowable Error

The Total Allowable Error = 7.0%

(based on biological variation, concept of Fraser and others)



Jansen and Slingerland, Clin Chem Lab Med 2010; 48(7): 1021-1027

Uncertainty (POC vs. Lab)

- Uncertainty in target value of the trueness verified method (=lab method)
- Uncertainty of imprecision
- Uncertainty of bias
- Uncertainty in total error

Jansen and Slingerland, Clin Chem Lab Med 2010; 48(7): 1021-1027

Allowable Error

- Total allowable error of POCT-meters versus an IFCC traceable laboratory method: ca.10%

Jansen and Slingerland, Clin Chem Lab Med 2010; 48(7): 1021-1027

ISO 15197
for home-use glucometers

- Still 15% deviation allowed!
- Only for home-use meters
- Differences glucose values in health-care chain!
- An IFCC workinggroup for glucose-meters in intensive care setting may create even more differences in glucose values.

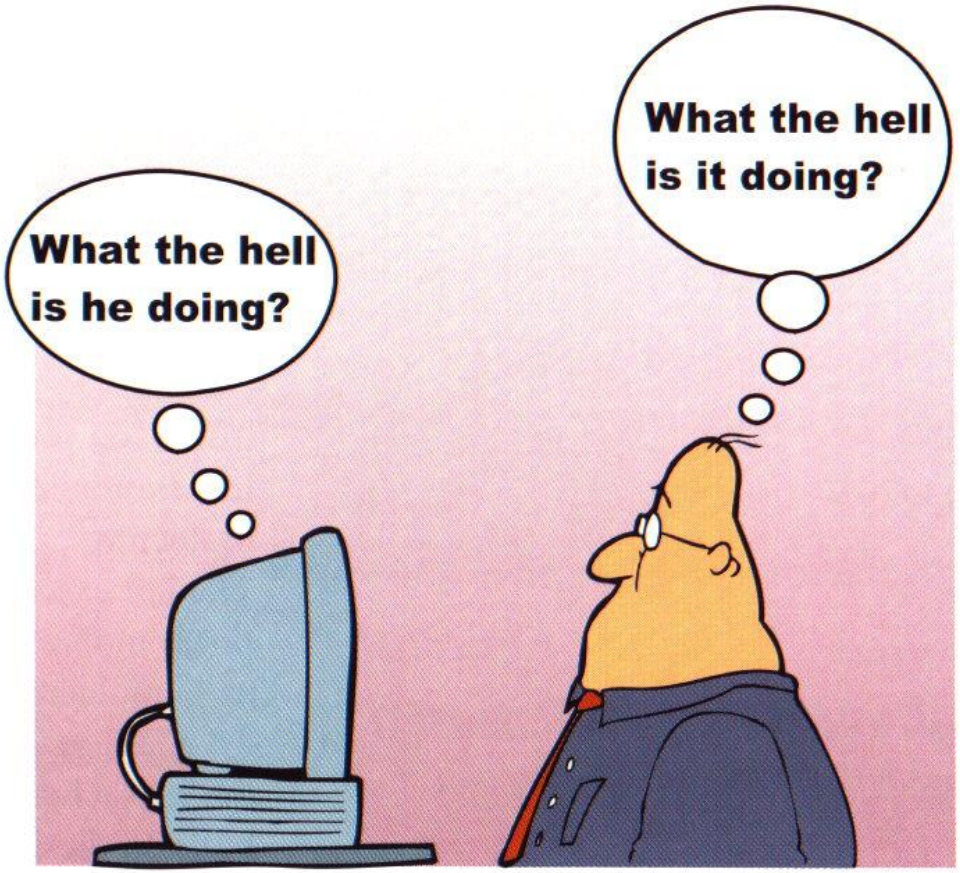
It is all water, but it is all different

Harmonised values in general

Minimal quality standard whole health-care chain:

- technically and economically achievable
- and based on most dangerous situation for patients
  - → likely the general hospital departments
  - → not the ICU: more checks, more feedback loops available

Performance of glucose meters in patients hands



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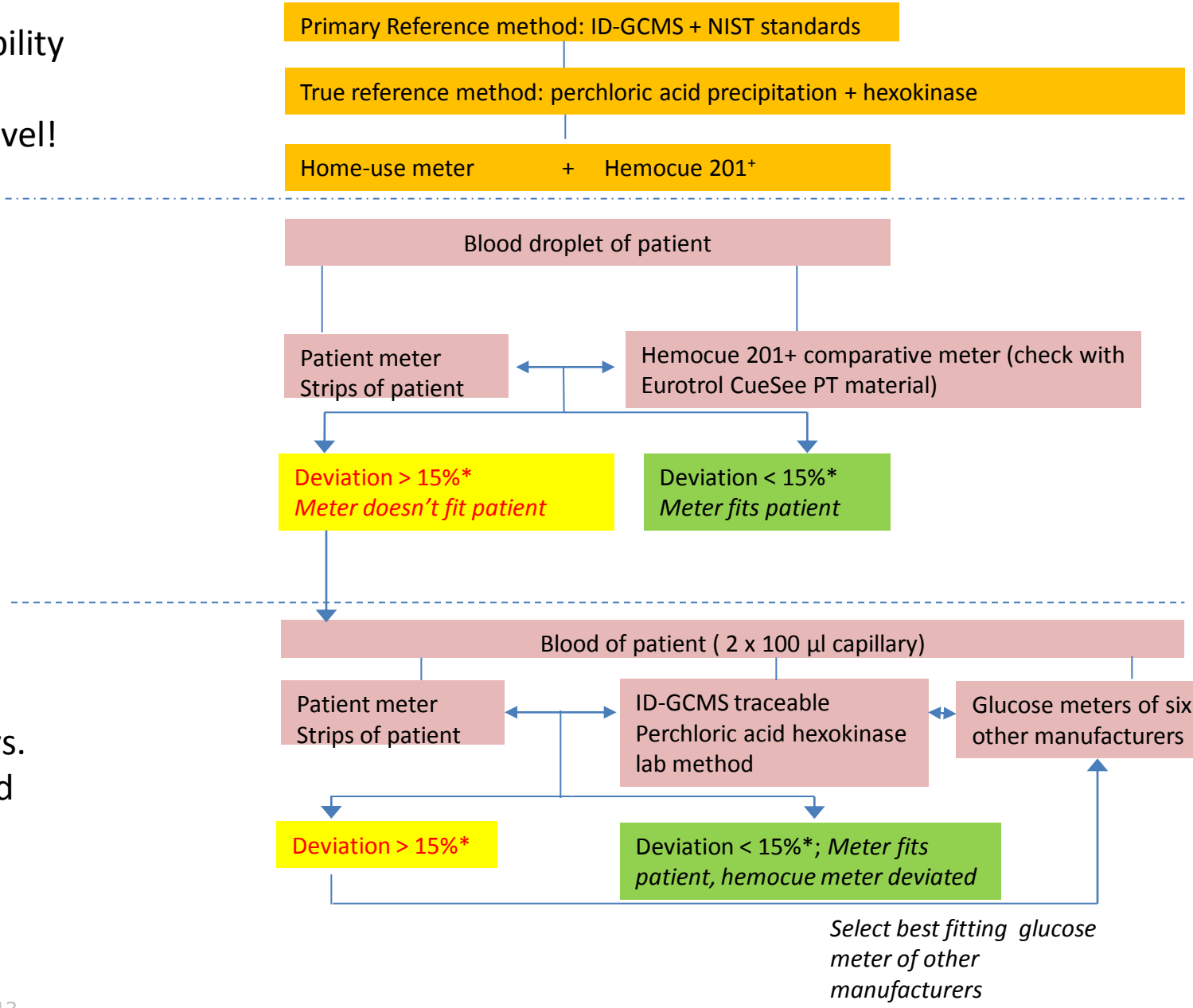
General traceability chain at manufacturer level!



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Check procedure phase	number
Yearly check-up glucose meters patients	2500
Deviating glucose meters patients vs. Hemocue 201^{+}	50
Deviating glucose meters patients vs. perchloric acid precipitation ID-GCMS traceable hexokinase method	25

Conclusion:

1% of the population glucose meter that doesn't fit →bad glucose control → pathology → overstretched health care system!

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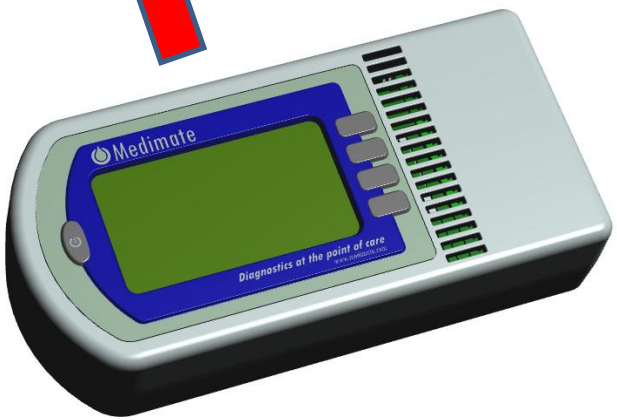
Changes in Diagnostics

- Diagnostics move closer to or into patient!
- POCT, POST or In-Patient Testing (IPT)
- Invasive and non-invasive Diagnostics
- Tele-diagnostics
- Nano-scale

Multipurpose POCT instruments

Hypertensie

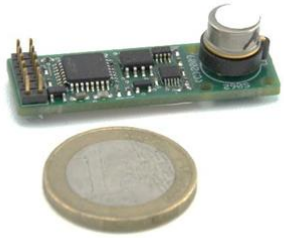
Nierfalen



Bipolaire stoornis

Hartfalen

Electronic-nose



- Dysruptive technology
- Non invasive
- Pattern recognition instead of Biomarkers
- Self learning system in case of internet based screening

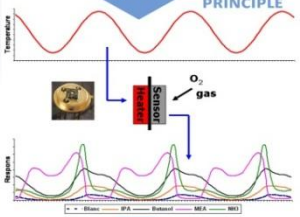
➢ TBC
➢ Cow mastitis

The eNose company
WWW.ENOSE.NL

Real-world Breath Analysis with AENOSE

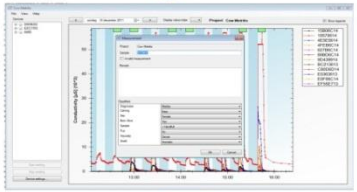
Intelligent nose module

PATENTED MEASUREMENT PRINCIPLE



DATA COLLECTION

DATA MANAGEMENT



MULTIWAY DATASET

32 x 32 x 3 PER SUBJECT

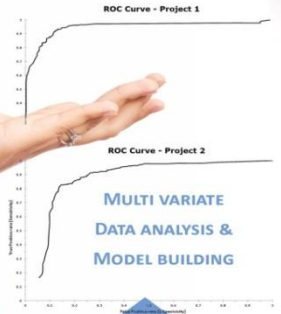
SCALING & COMPRESSION

AEONOSE AND AEOLUS BRING TAIL WIND

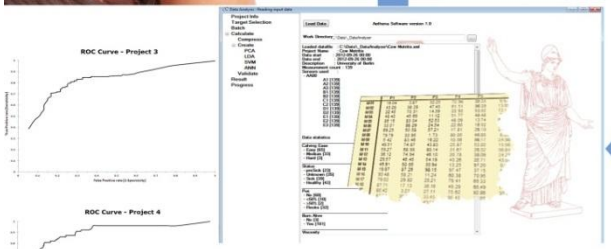
WHAT'S IN A NAME? THE NAME AEONOSE IS A PLAYFUL REFERENCE TO GREEK MYTHOLOGY, TO AEOLUS WHO WAS APPOINTED AS KEEPER OF THE WINDS BY ZEUS. AEOLUS KEPT THE WINDS IN A CAVE AND LET SOME OF THEM ESCAPE WHEN REQUIRED. HE COULD USE HEAD WIND TO PREVENT THINGS FROM HAPPENING, BUT ALSO SUPPLY TAIL WIND TO SPEED UP PROCESSES.

AEONOSE COULD JUST BE A BROTHER OF AEOLUS. AEONOSE MIGHT NOT BE A DEITY, BUT IT IS A COLLECTION OF TECHNIQUES WHICH MIGHT GIVE YOU SOME TAIL WIND.

ON REQUEST (IF COMMERCIALLY VIABLE) EMBEDDED MODELS FOR REALTIME ANALYSIS



MULTI VARIATE DATA ANALYSIS & MODEL BUILDING



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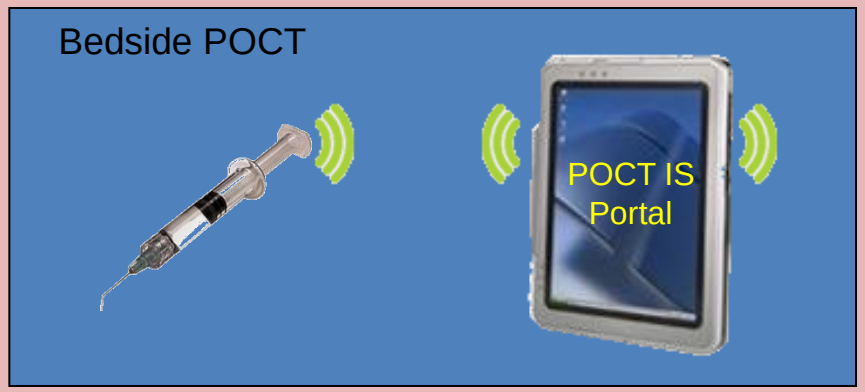
The eNose company

Visions/Challenge of the Future

- Wireless rules
- Transform home-use measurement data into health information



POCT IS Server

POC-DNA-sequencer

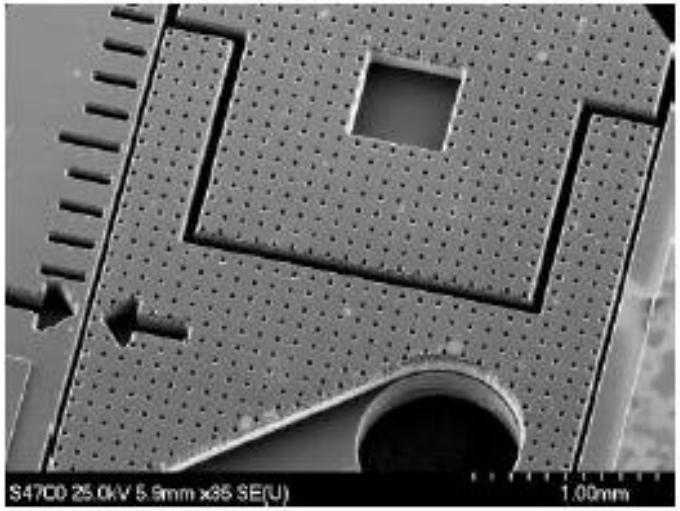
- Only for professionals yet!
- Bacteriophages
- Humans?

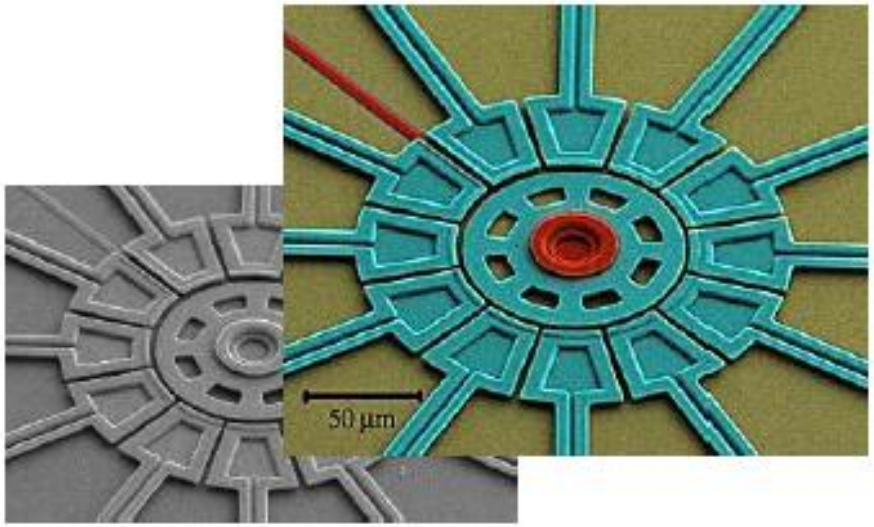
MinION - $900 usb-powered DNA sequencer

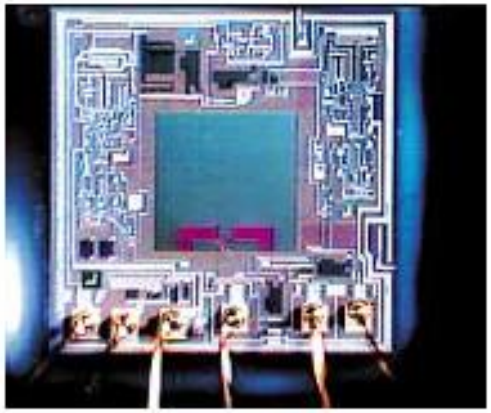
http://www.newscientist.com/article/dn21495-usb-stick-can-sequence-dna-in-seconds.html

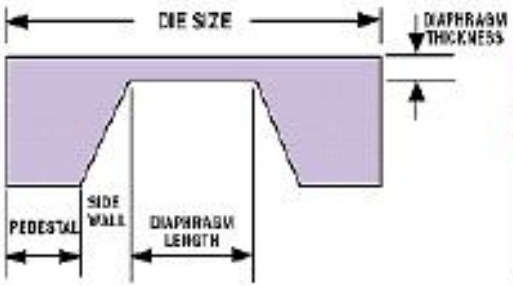
MEMS

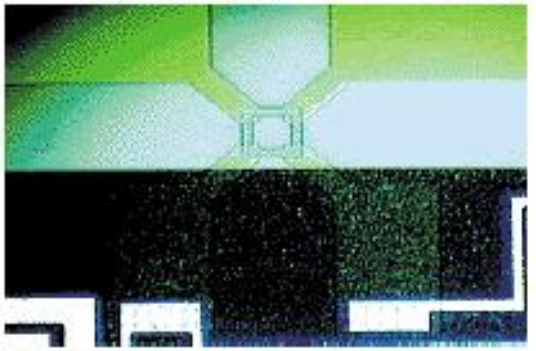
- Micro-Electro-Mechanical Systems (MEMS) is the integration of mechanical elements, sensors, actuators, and electronics on a common silicon substrate through microfabrication technology.
- The micromechanical components are fabricated using compatible "micromachining" processes that selectively etch away parts of the silicon wafer or add new structural layers to form the mechanical and electromechanical devices.
- For mass production of microstructures with controlled quality







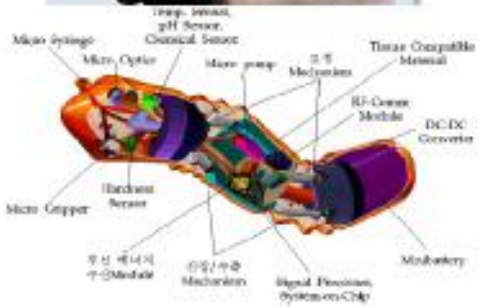




Disposable pressure transducers

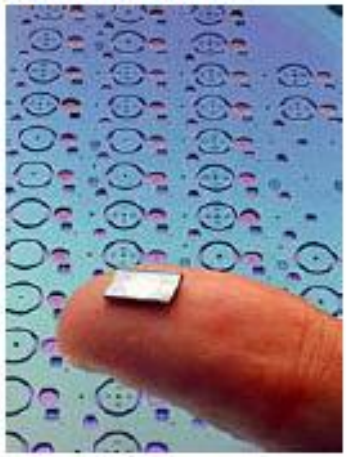
MEMS
in Medical Devices

Accelerometer

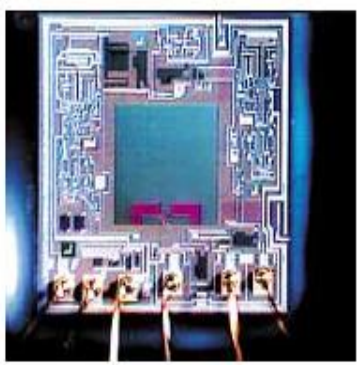


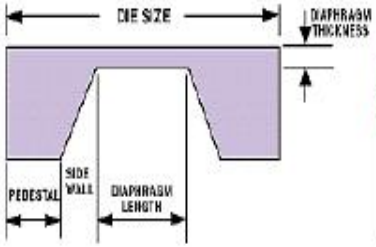
Wireless Capsule Endoscope

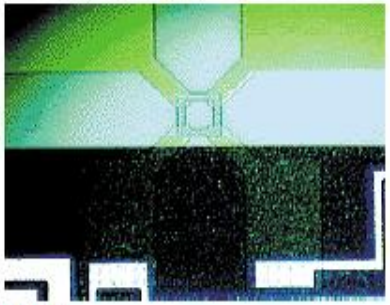
DEBIOTECH, Swiss
Insulin pump



Lab-on-a-chip?







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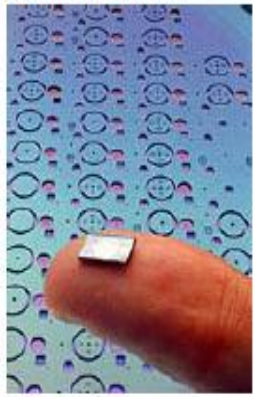
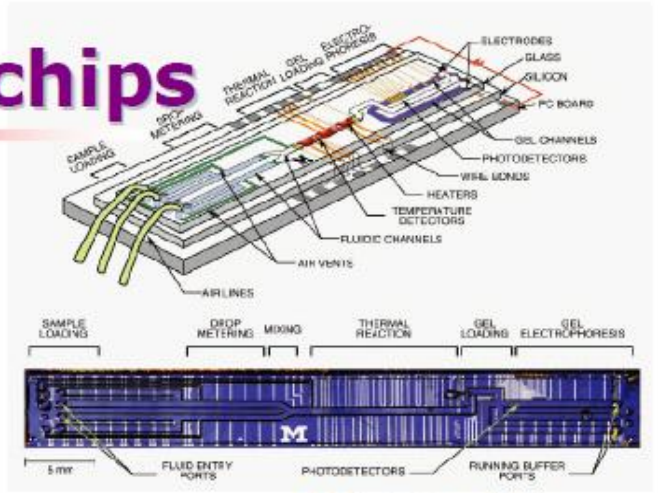


Lab-assay chips!

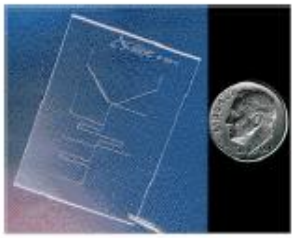
GeneChip, Affymetrix



Lab-on-a-chip, Michigan Univ.

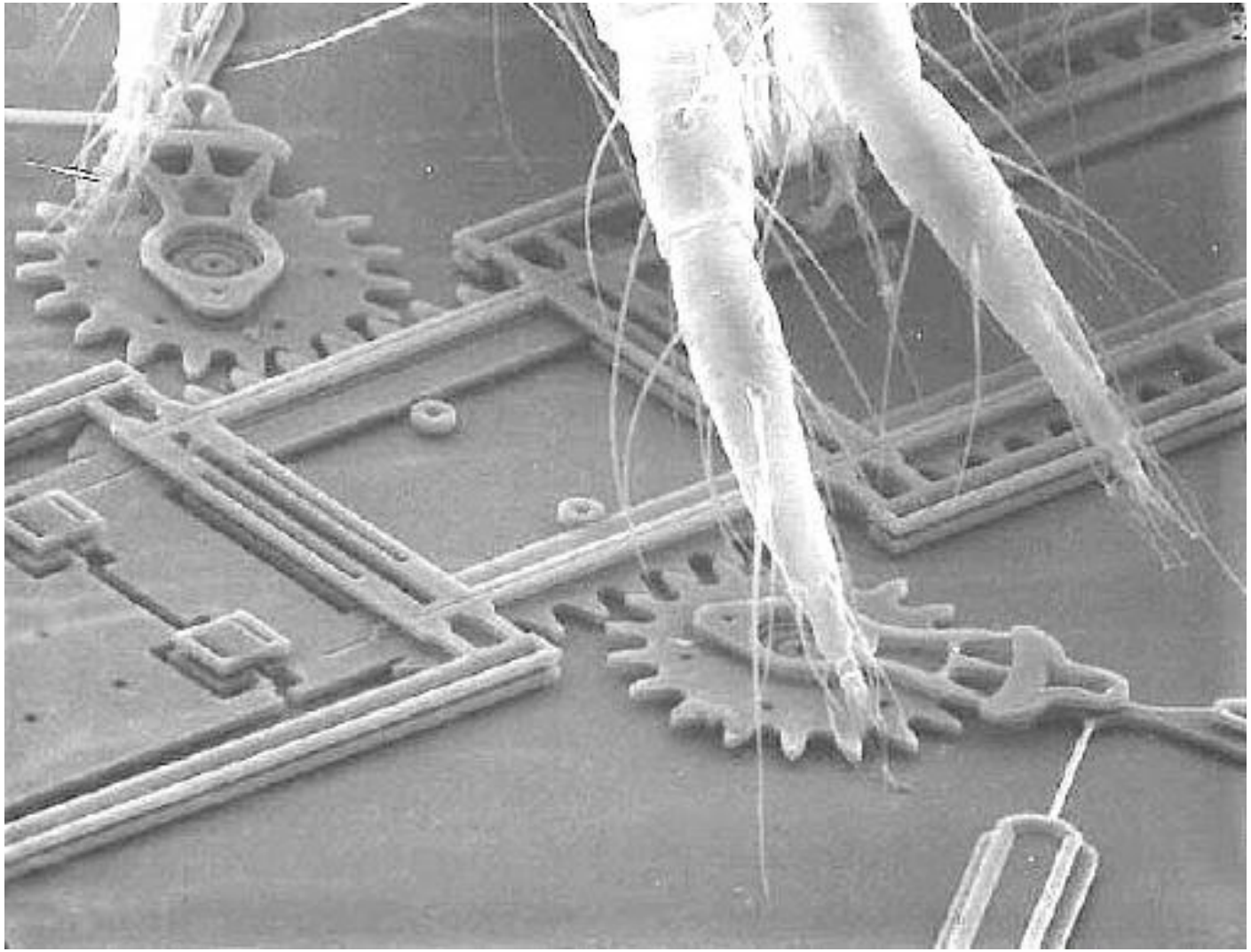
DNA chip, Macrogen

HPV DNA chip, Biomedlab



Labchip, Caliper Tech.

We need smaller!



Challenges

- Patient or professional push / cost or benefit?
- 10% deviation glucose value!
- Harmonised Values Health Care Chain
- 1% of glucose meters does not fit patient
- New developments (Multi-disease/Non-invasive/translating data/Smaller)