High Density Packaging for (Wrist) Wearable Medical Devices (WMDs)

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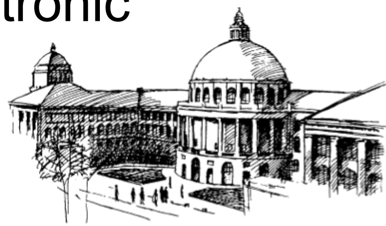
Who is Art of Technology

- Has its roots in the EU project EUROPRACTICE (1995), whose purpose was to disseminate the HDP/MCM technology in Europe.

EUROPRACTICE
MCM SERVICE

- Key personel experienced in miniaturization of electronic systems since 1996 .



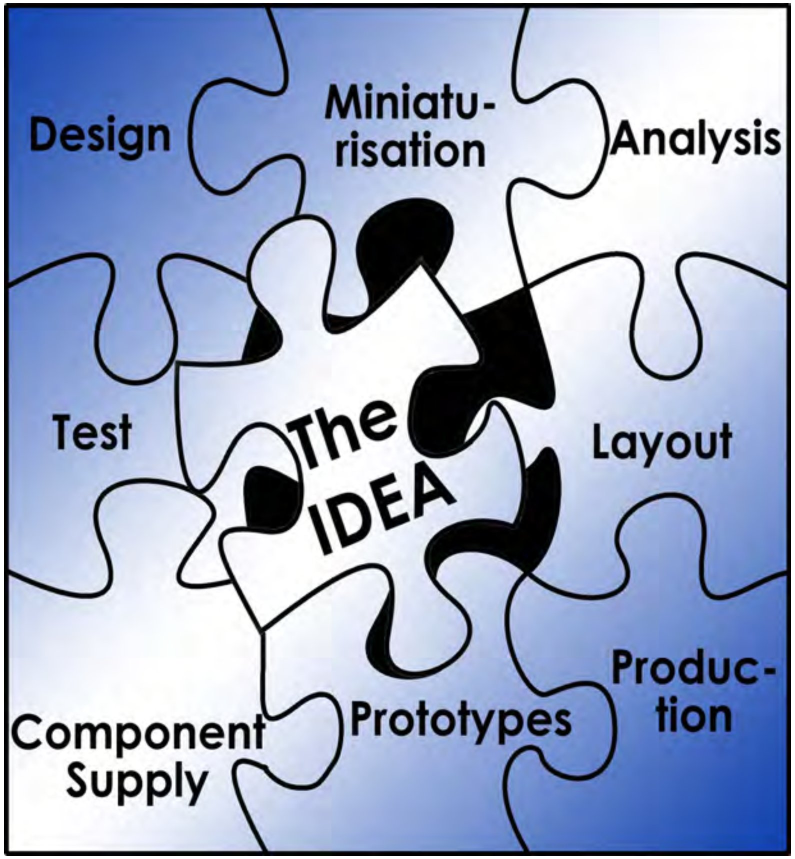
- Company was founded in 1999 as ETH spin-off.
- 80% commercial contracts and 20% EU funded projects.
- Successful work assignments in the
  - Medical, Aerospace, Fixed and Wireless Communications, Sensor Technology, Computer and many other industries
- Privately held company with strong partnerships.
- Certified QS-System:
  ISO9001:2000 and ISO 13485:2000 (medical)

Zertifiziertes Managementsystem
SQS
ISO 9001:2000 / ISO 13485:2000

The Services of Art of Technology

Art of Technology offers a turn-key service to transform customer ideas into products:

- Development of ideas and solutions
- Basic research
- Feasibility studies & technology evaluation
- Component Procurement
- System design incl. firmware
- Layout & production preparation
- Evaluation of manufacturers and accompanying of the production
- Test & qualification



... using HDP/MCM Miniaturization Technologies!

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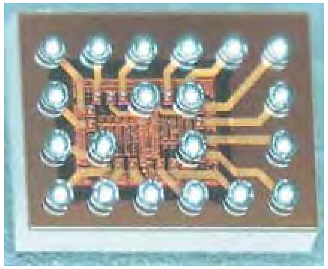
Agenda

- **High Density Packaging**
- **Medical Electronic Devices**
  - Classification
  - New application areas enabled by HDP/MCM
- **(Wrist) Wearable Medical Devices (WMDs)**
  - Market requirements and design challenges
  - Application examples
  - Design conclusions
- **Biocompatibility**
- **Implants**
  - Even smaller than WMDs
  - Requirements & technologies
- **Summary**

What is High Density Packaging (HDP/MCM)?

HDP-Modules are built using

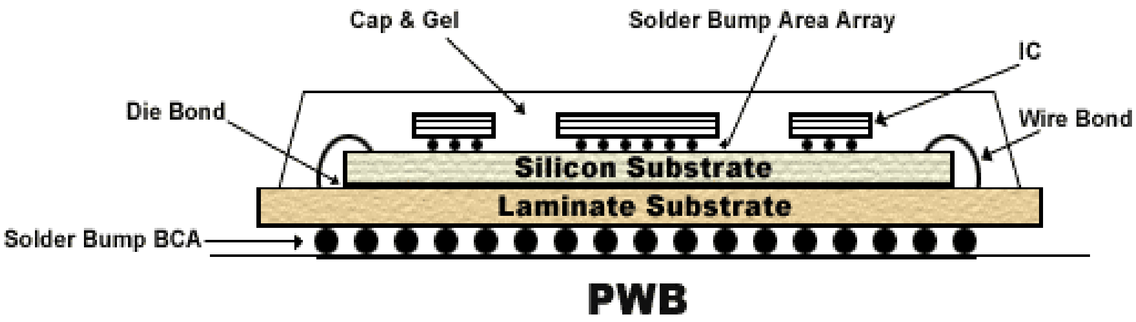
- Bare dies (un-housed ICs)
- µ-BGAs or Chip-Size Packages (CSPs)
- Highly integrated circuit boards (substrates)
- Different assembly technologies



Picture: source FhG-IZM

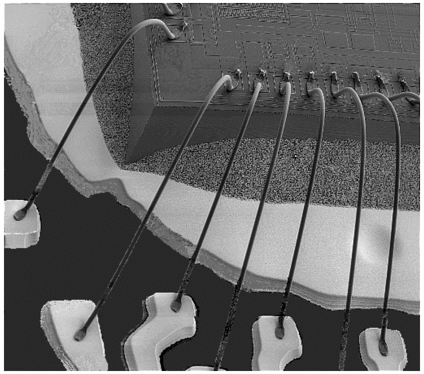
An HDP-Module is

- either a complete system/device
- or part of a system packed in a PGA or a BGA and then mounted on a PCB

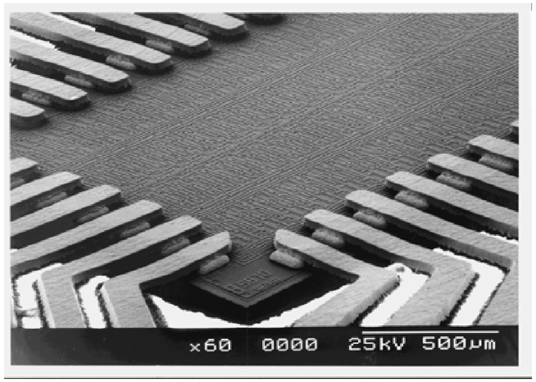


Assembly Technologies

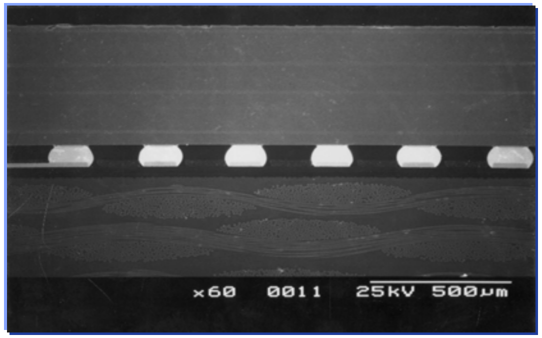
Wire bonding



Tape **A**utomated **B**onding

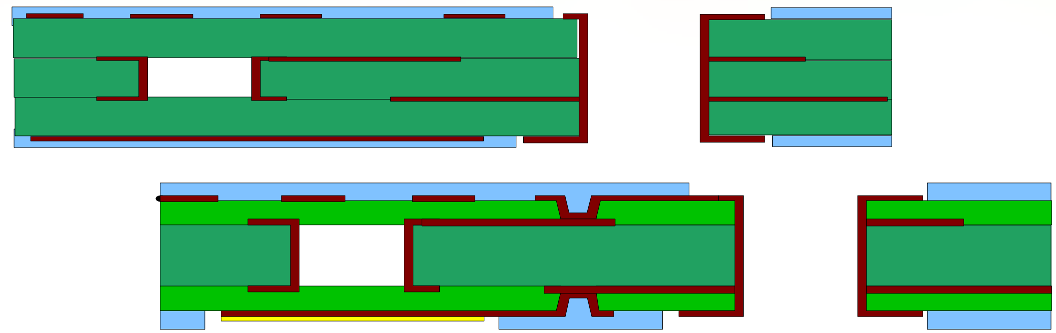


Flip Chip

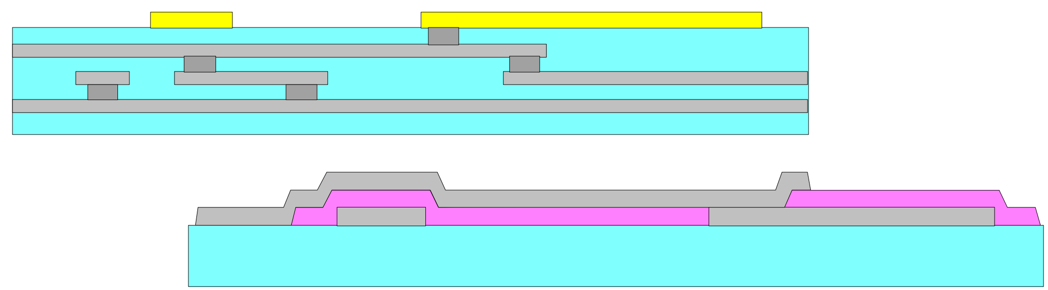


Substrate Technologies

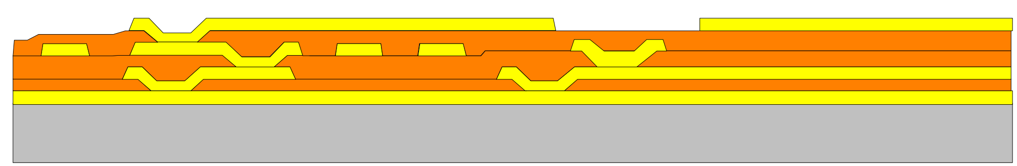
Laminate
(PCB/SBU/Micro Via)



Ceramic
(Co-fired / Hybrid)



Thin film
(on Silicon, Ceramic, Glass, Laminate)



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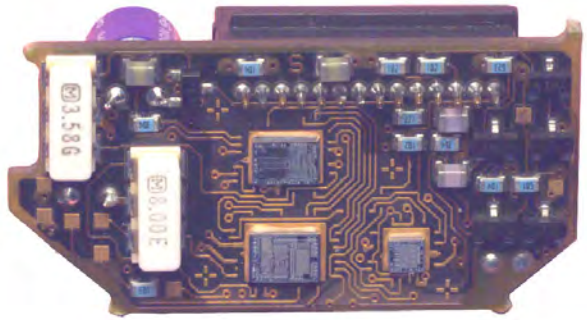
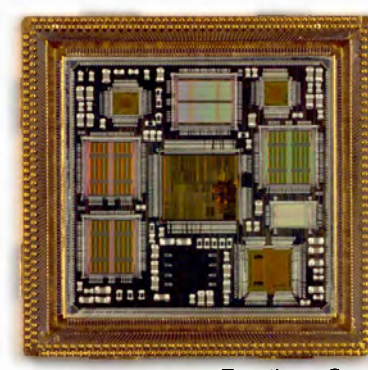
Sample Miniaturization Technologies

Miniaturization of electronic systems through High Density Packaging (HDP/MCM)

COB
Chip on Board



Accu Charger f. Mobile Phone



Pentium Core-Module

1 cm

MCP
Multi Chip Package

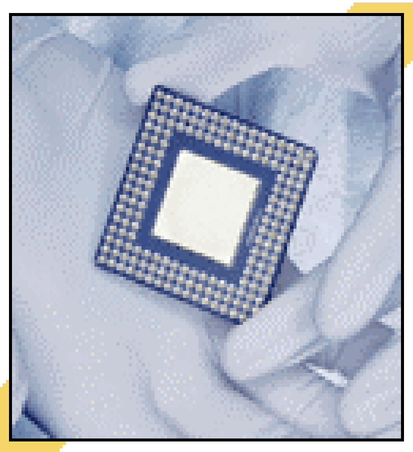
Why Choose HDP/MCM?

Advantages of the HDP/MCM-Technologies :

- Shorter development times and overall faster time to market than an ASIC
- Increase of functionality while reducing size and weight
- Increased performance
- Reduced power consumption
- Cost reduction at system level
- Easier protection against EMC and EMI
- High reliability
- Increased modularity and reusability of subsystems

Where to use HDP/MCM?

HDP/MCM Application areas include



- All applications where many features need to be integrated into a small, lightweight, low-power – often mobile or wearable – device.
- Applications in mixed-signal electronic systems as an alternative to a costly, risky and time-consuming ASIC design.
- If you already have designed ASICs, HDP/MCM will allow you to efficiently and inexpensively use them to offer a wide range of product variations.
- Applications to be used under extreme environmental conditions such as temperature, electromagnetic interference etc.

Ranking Medical Electronic Devices

- **Laboratory/Hospital equipment**
  - Large-scale, expensive equipment
  - Used in leading-edge diagnosis and patient care
  - Not covered in this talk

- **(Wrist) Wearable Medical Devices (WMDs)**
  - Truly portable medical devices
  - Miniaturization of laboratory equipment through HDP/MCM
  - Patients become independent of location (hospital) and professional care (physician)

- **Implants**
  - Smaller but more complex
  - Further improve patients‘ comfort

New Wrist Wearable Medical Devices (WMDs)

New Applications: Not only a transient phase from laboratory equipment to implants: they made a functional quality leap from simple measuring aids (replacing physicians) to complex services including diagnosis support.

New Technologies: Fostered by new sensor concepts, miniaturized signal processing and communication capabilities.

New Players: Nowadays also SMEs can develop innovative WMDs.

Market Requirements & Challenges for WMDs

Small and lightweight

- Small enough to fit around the wrist
- Shall be unobtrusive, and not necessarily look like a medical device

Low power

- Stand-alone power supply of minimum 15 hours (1 working day).
- Low power consumption (e.g. HRM): Primary battery
- High power consumption: rechargeable (enforces connectors, battery protection circuit, massive regulatory issues)

Life cycle and housing

- MTTF 4 years, "no consumer device"
- Shock proof, at least splash water resistant (IP65)
- Biocompatible with skin contact (FDA approval)

Requirements & Challenges for WMDs II

Interconnection

- Connectors complicate mechanical design and production
- Wireless solutions demand a higher power budget

(Novel) sensors

- Cannot be easily integrated into standard electronics and housings
- Biocompatibility issues can influence the measurement path
- Analog control and signal processing cannot be easily miniaturized.

$\Downarrow$

There is no ultimate solution to be presented, every device means a carefully evaluated optimum!

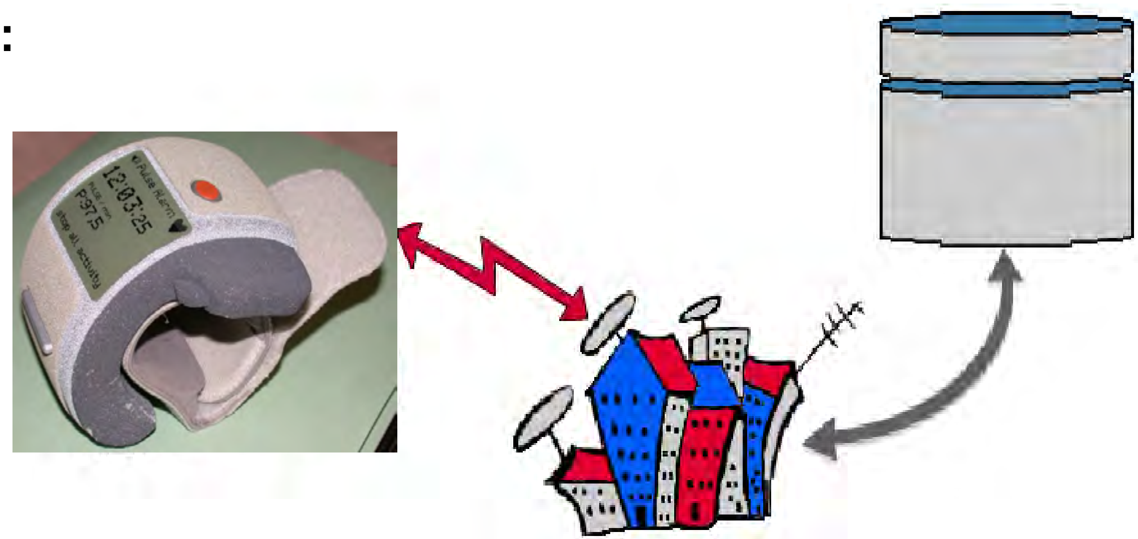
Application example AMON*)

Project‘s Goal (30 months):

- Wrist wearable monitoring device for heart patients
- Bi-directional link to telemedicine center, online diagnosis

Variables monitored :

- Body temperature
- Blood pressure
- Blood oxygen
- ECG
- Heart rate
- Heart rythm



additionnal Features:

- Emergency button
- Mobile phone

ETH Eidgenössische Technische Hochschule Zürich

TADIRAN SPECTRALINK LTD.

MDirect

AURELIA Microelettronica S.p.A.

ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

*) Advanced care & alert telemedical Monitor, EU Project

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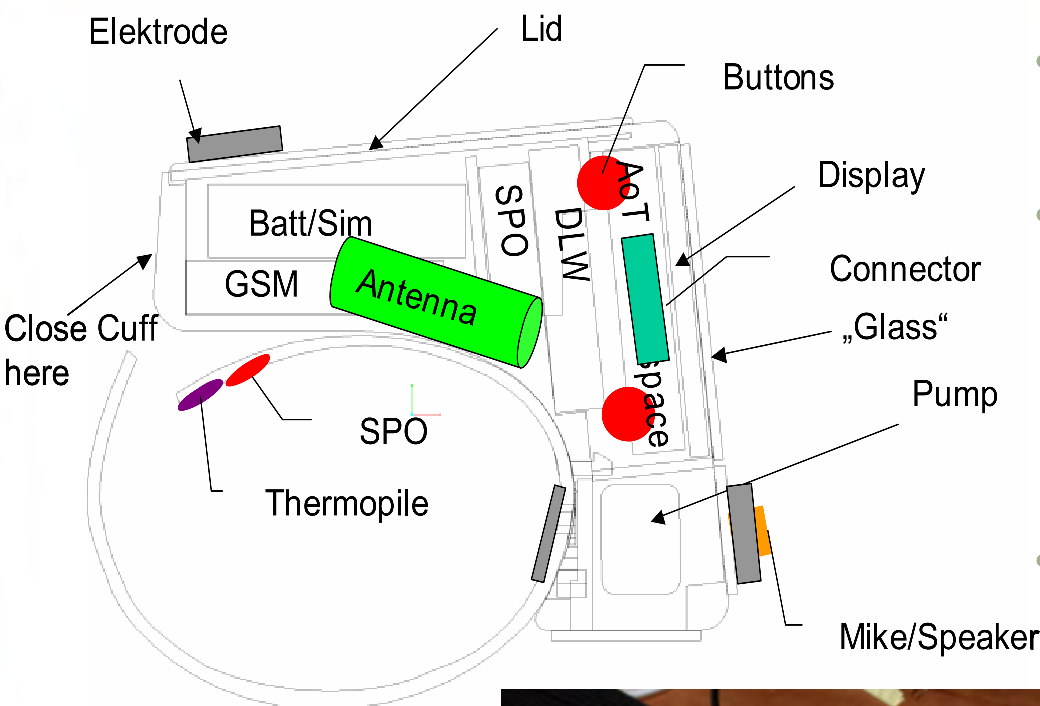
AMON - Technology

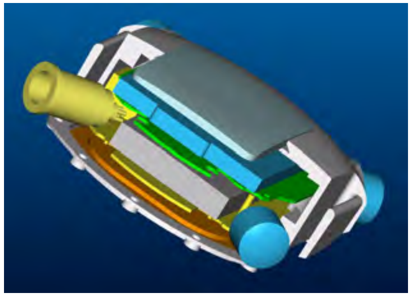


- New functional SMD prototype produced
- Integration of standard building blocks (SPO2, GSM) to achieve functional validation
- Future revisions could concentrate on block integration and height reduction using HDP

AMON – The new functional Prototype

Application example Pendra ®

- Wrist wearable novel non-invasive glucose monitoring device (obtained CE mark in May 2003)
- Developed jointly with Pendragon Medical, Switzerland from Research to Series Production
- Immediate attainment of targeted form factor was mandatory → HDP/MCM
- Consists of:
  - Digital control board with User Interface
  - Battery
  - Analog measurement electronics
  - Sensor

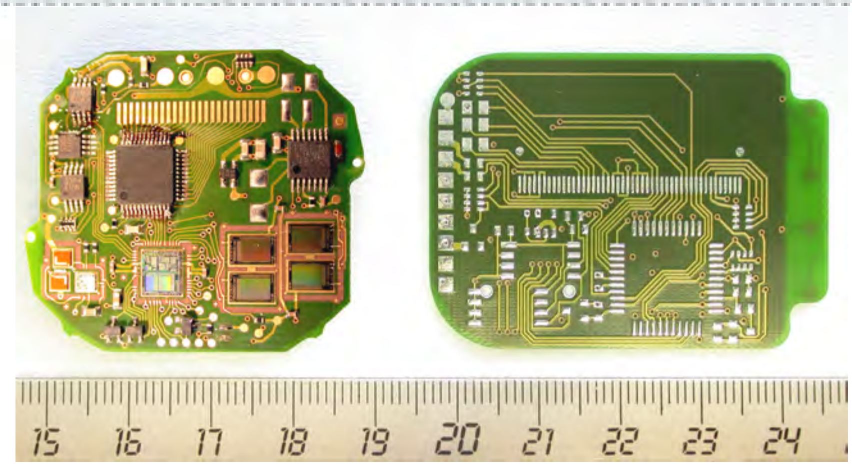


Pendra® - Technologies

Prototype P1: SMD	Prototype P2: COB	PreSeries: COB
Contains: -uC -2 Data memories -Power converter	Contains: -Battery Protection -4 Data memories -Display controller -Backlight & Buzzer	Contains: -Additional Components as COB -More functionality on less space
	-COB -uC, Battery Protection, memory	-Improved connector solution, reduced height (but case is rounded)
-Board: 45 x 50 mm^2 -Case: 60 x 45 x 12 mm^3	-Board: 35.5 x 41 mm^2 -Case: 45 x 45 x 12 mm^3	-Board: 33.1 x 42 mm^2 -Case: 51 x 38 x 13 mm^3

Pendra® - Size comparison

Size of the Control Board (left P2, right P1)



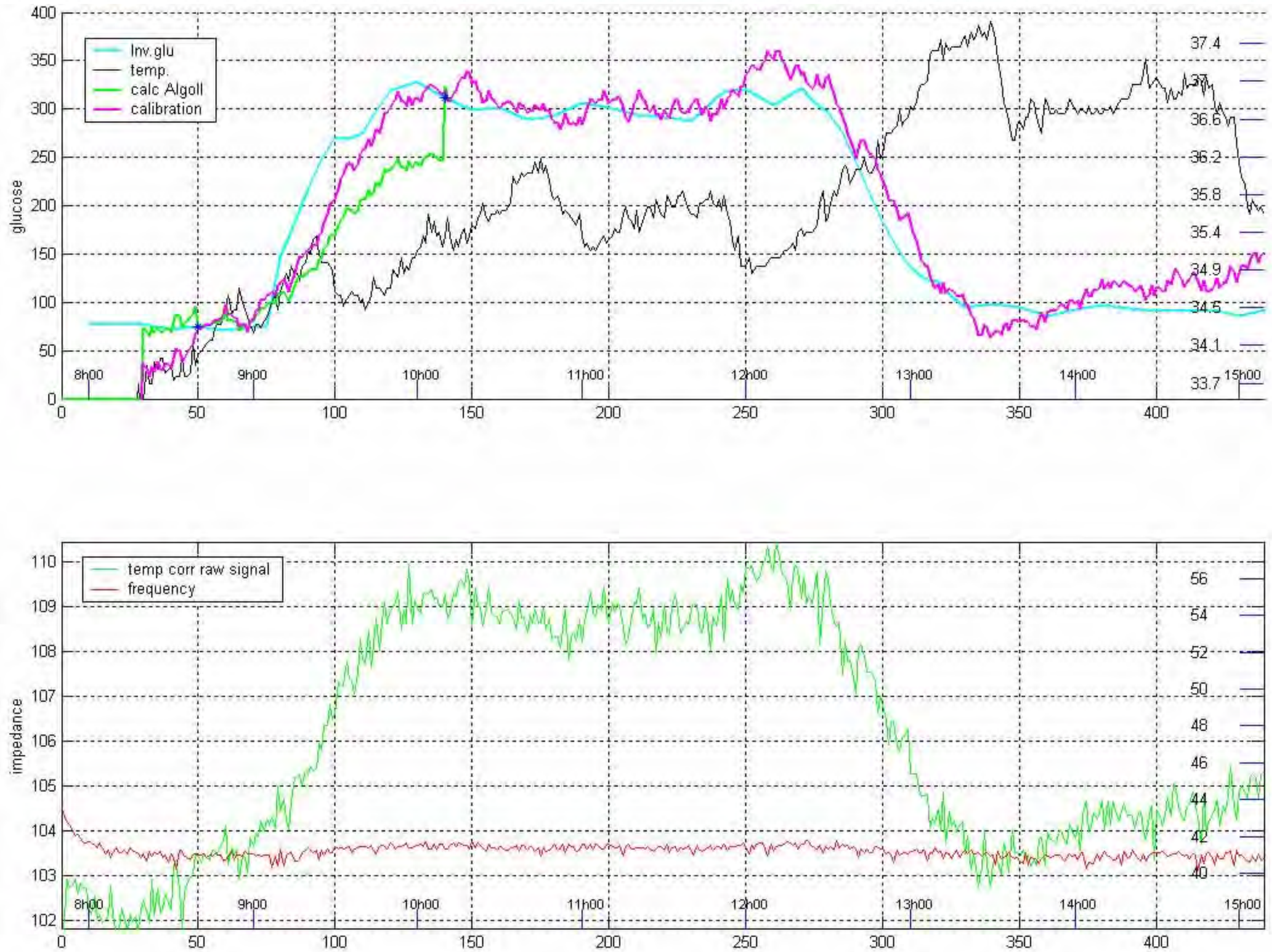
P1

P2

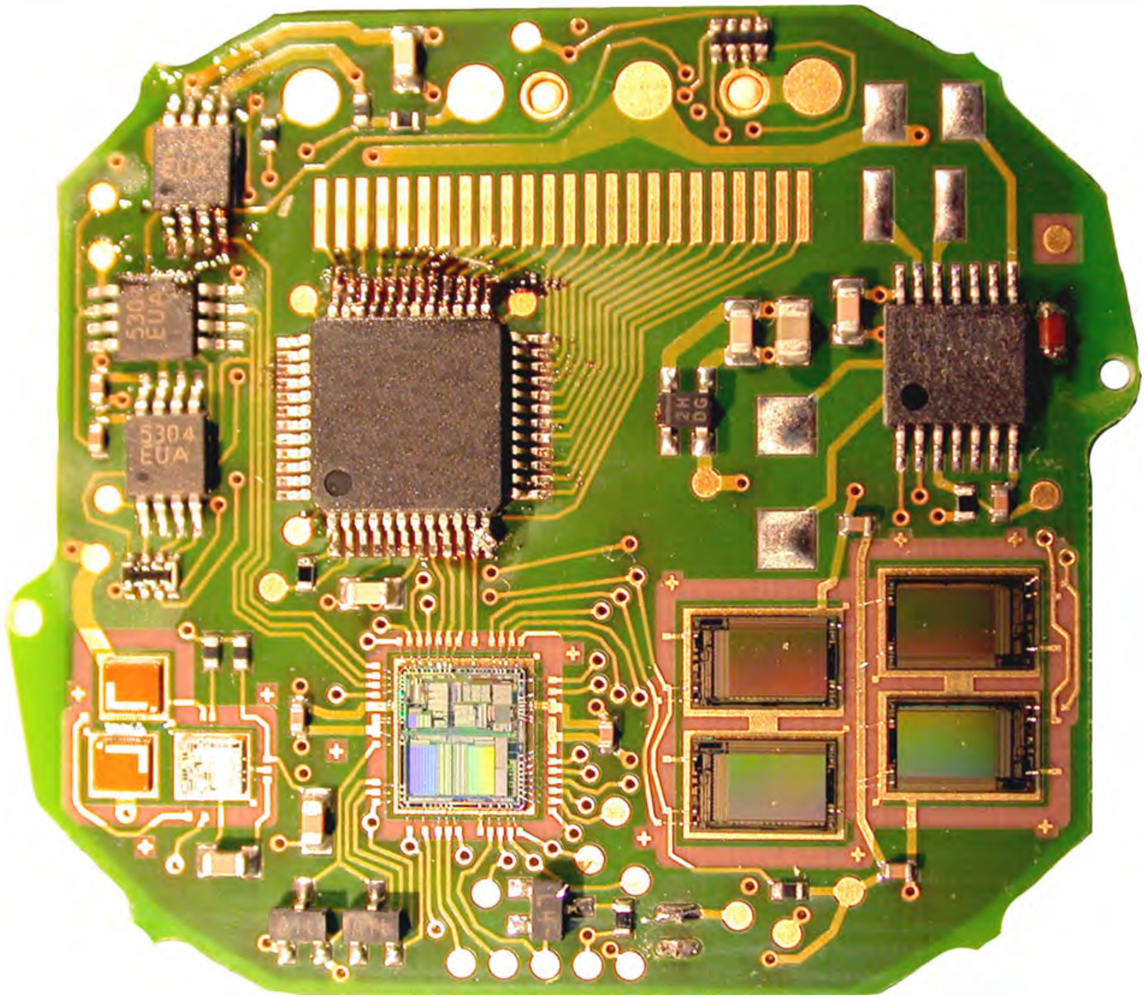
PreSeries

Outer enclosures

Pendra® - Results



Pendra® - HDP Technology



Pic © Pendragon Medical

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Other Wearable Approach

• QBIC Belt Integrated Computer

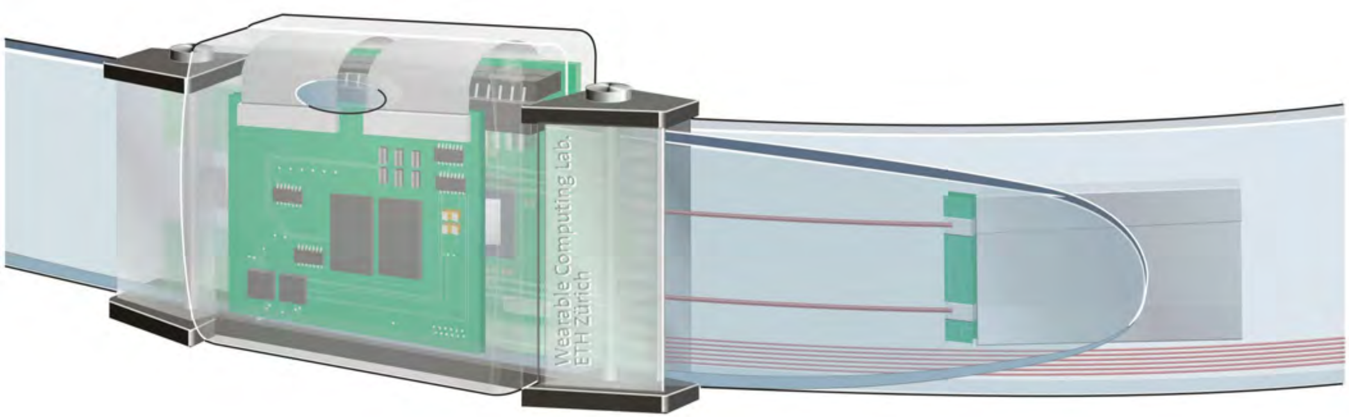
Wearable Computing Lab.
ETH Zürich

Applications

- Wearable PC
- Central Data collection and Processing
- Many other

Designed to Wear

- Fully integrated in a Belt
- Processor, Wireless Communication and Memory in the Buckle
- I/O-Plugs and Battery integrated in the Belt



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Other Wearable Approach

- **QBIC Belt Integrated Computer**

Wearable Computing Lab.
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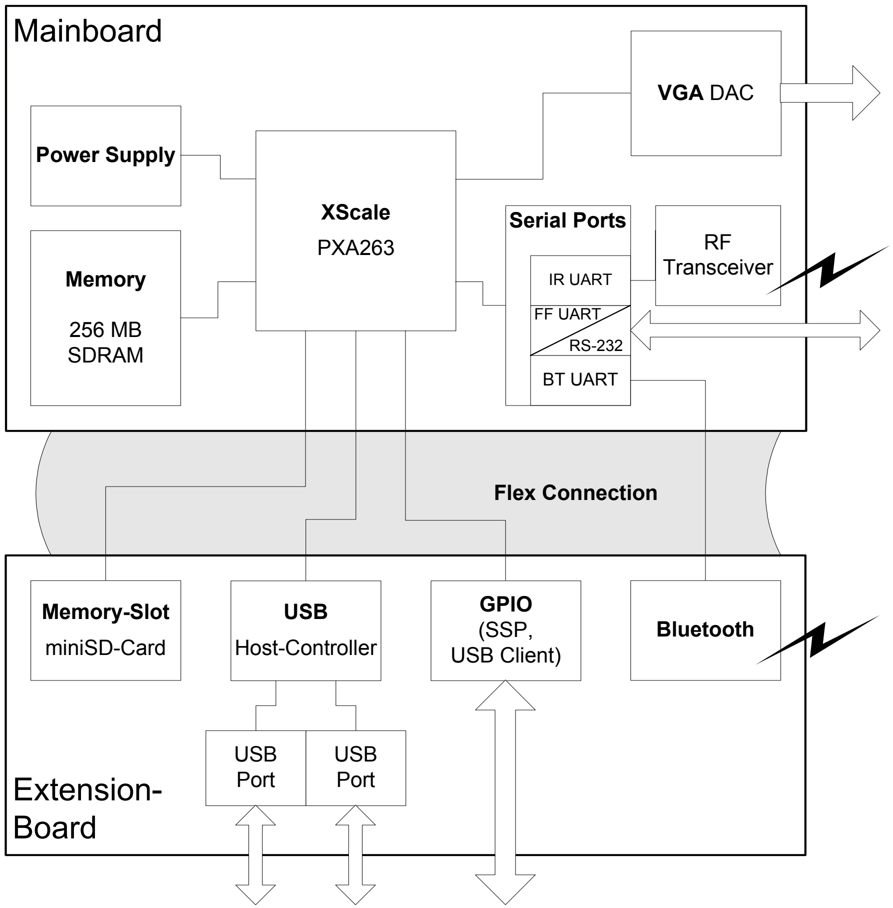

Key Features

- **Low Power**
- **Small Size**
- **Flex Connection**
- **Standard Interfaces**
    - **USB, RS-232, RF VGA, Bluetooth**

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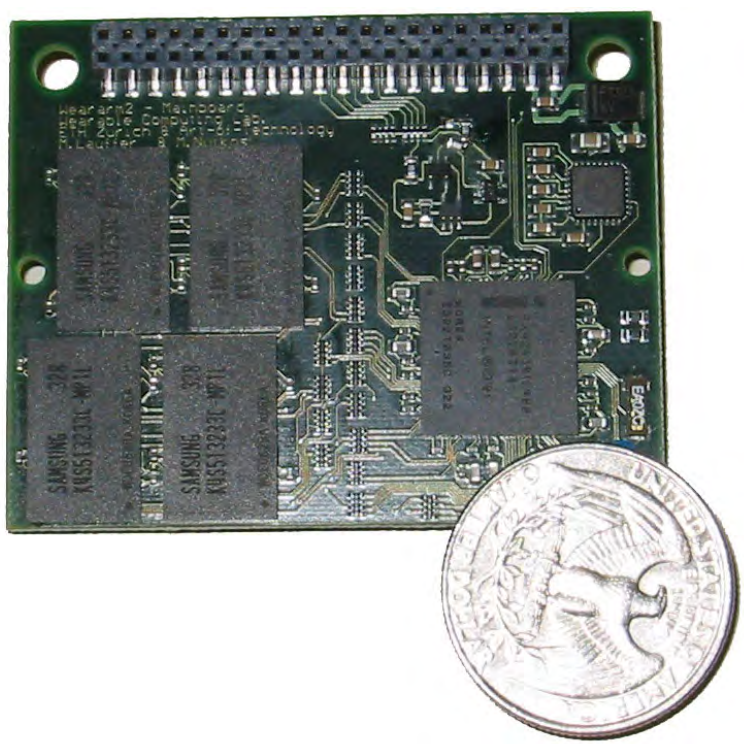
Other Wearable Approach

QBIC Belt Integrated Computer

Wearable Computing Lab.
ETH Zürich



- **Technologies**
  - **Chip Scale and Chip Size Packages (CSP)**
  - **HDP Substrate 8 Layers featuring four Microvia Layers (Laser)**
  - **Star-Flex Print for Extension Board**

Conclusions WMDs

- **Functional prototypes should already be (wrist) wearable**
  - Makes prototypes more complicated and requires close cooperation with mechanical engineering.
  - But helps testing user interaction (esp. for sensors) and minimizes unexpected setbacks when moving to the targeted form factor.
- **„Building block strategy“ (AMON)**
  - Looks favorable: existing submodules can be relied on (e.g. for communication).
  - Drawback: double work for later superfluous interfaces (cables) and mechanics, SW integration could become a serious inconvenience.
  - Although rather bulky, it works on standard PCB/SMD technology.
- **Complete custom development (Pendra®)**
  - More effort is needed in the first stages.
  - But all pieces fit neatly together, there is no double HW.
  - HDP/MCM is a must when targeting a "marketable" form.

Conclusions WMDs (II)

- **HDP/MCM Advantages**
  - Size reduction (smaller footprint)
  - Low-profile (1-1.5 mm per layer, using Bare Dies, other substrates instead of 2-2.5 mm)
  - Less weight (less packaging overhead)

- **Further Challenges**
  - Sensors are often not standard for wrist portability, further research is needed.
  - Skin-contact effects must satisfy regulatory (CE, FDA) requirements.
  - How to interface the device, when downloading data or charging the batteries?
  - WMDs can be built with standard electronics assembly technologies, (except for sensors), and mechanics is the most complex aspect.

Biocompatibility

- **Requirements (ISO 10993)**
  - Stable in physiological environment, no degradation over time
  - Protecting electronics against body fluids and humidity
  - Non-toxic or isolating toxic materials
  - Smooth surface, not inducing traumas, must not brittle, light-weight, flexible, must conform the natural soft tissue
- **Housing (hermetic)**
  - Metal (Steel, Titanium, Platinum)
  - Ceramics or Glass
- **Coatings**
  - Silicone (very flexible, but not long-lasting)
  - Parylene (some μm), tight against body fluids and humidity
- **Molded plastics**
  - Macrolone (robust and FDA approved)
  - Polystyrene, PMMA, PEEK, Polycarbonate and Polypropylene, ABS

Design Challenges for Implants

- **Minimum size:**
  - An implant is still an "artificial element" in the body
- **Minimal power consumption**
  - Target is primary battery, non rechargeable, but battery replacement means surgery!
  - The future: charging via inductive coupling
- **Highly reliable**
  - Implants are supporting vital functions, again replacement means surgery
- **Flexible**
  - Electronics must meet environmental requirements, and not vice versa

Design Challenges for Implants (II)

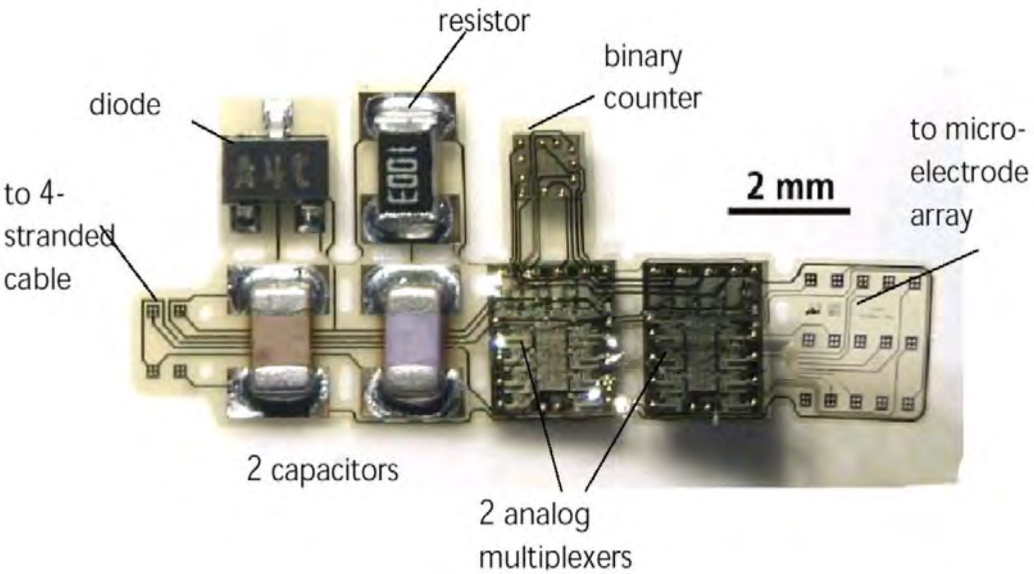
- **Encapsulation**
  - Biocompatible, FDA approved
  - Protecting the electronics against aggressive fluids and humidity
  - Mostly hermetic sealing
  - But still enabling communication to externals (Data downloads)

- **Technology**
  - Requires special encapsulation, even aggressive electronics build up/packaging for miniaturization → HDP/MCM

Example Nerve Cuff Electrode FhG-IBMT*)

- **18 channel electrode for recording neural information**
  - Combination of Si and Thinfilm PI

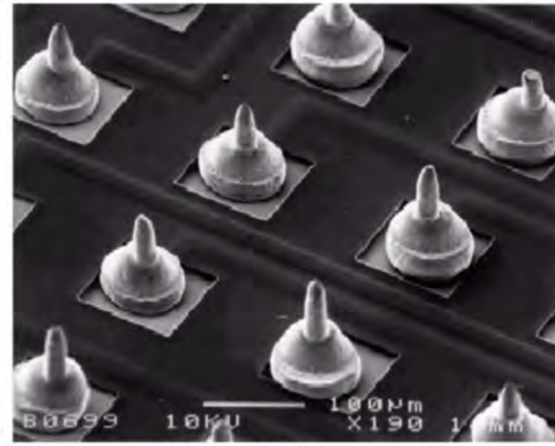
- **Multiplexer**
  - Thinfilm PI-PCB
  - 3 dies, 5 SMDs
  - Silicone encapsulation
  - Reduced # cables to 4

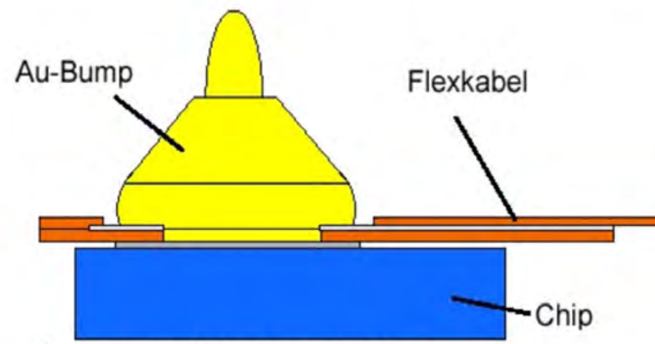


Pics courtesy Fraunhofer-Institut für Biomedizinische Technik

Nerve Cuff Electrode - Technology

- **Flex Substrate**
  - Hardened Polyimid PYRALIN PI 2611
  - Ti-Pt Metalization
  - Line width ≥ 5 µm
  - Pitch ≥ 10 µm
  - Bend radius of the substrate: ≥ 100 µm
- **Microflex connection**
  - Biocompatible
  - 100 µm pitch possible


Rasterelektronische Aufnahme eines Kontaktarrays



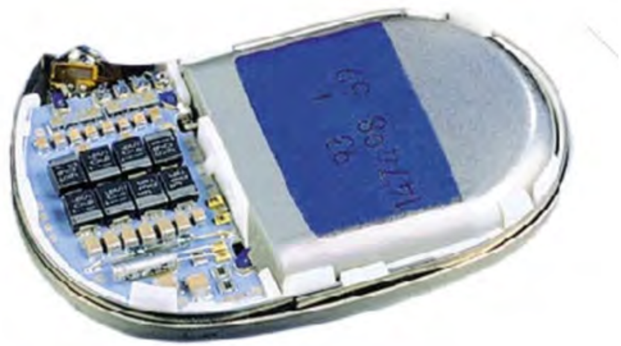
Skizze einer Mikroflexverbindung

Pics courtesy Fraunhofer-Institut für Biomedizinische Technik

Example Pace Maker

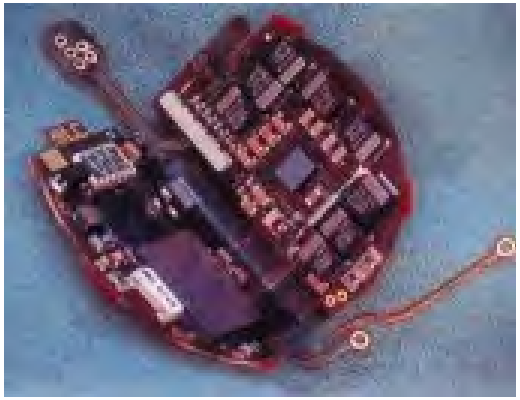
- **Standard technology**
  - Hybrid SMD
  - Possibly wire bond
- **Largest part:** Battery
- **Reducing the electronics:**
  - Wafer-level CSP
  - SMT Assembly w/ Underfill
  - 2-layer rigid-flex (Dycostrate)
  - Metal casing

Standard pace maker from Biotronik



Pic © Biotronik

Test development from FhG-IZM, MSE, Dyconex



Pics courtesy Fraunhofer-Institut für Mikrointegration & Zuverlässigkeit

Conclusions Implants

- **HDP/MCM advantages:**
  - Extreme miniaturization enables an improved implant technology.
  - Simplifies encapsulation by
    - Reducing volume
    - Being directly biocompatible
  - Improves biocompatibility
  - But special technologies require special regulatory approval
- **Important points**
  - Reliability increases (less solder connections)
  - But needs to be proven for every new build-up (no verified standards).
  - Power supply: Size (autonomous, non-rechargeable, long lasting battery) vs. Safety (small, short-range, rechargeable, but requiring reliable users/charging procedures)

Summary

- **Demonstrated that WMDs open new markets**
- **Detailed the design challenges for WMDs**
- **Presented two application examples for WMDs:**
  - HDP/MCM reduces volume and weight, thus simplifying housing/encapsulation
  - HDP/MCM prototypes seem to be more complicated, but reduce double design efforts and enable a faster prototype-product transition
  - Additional HDP/MCM production cost is manifold offset by the design and regulatory approval effort
  - Packaging has to ensure biocompatibility in all electronics-human interfaces:

    Encapsulation, Housing, Sensors

Thank you for your attention!

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