



Medizin- und Informationstechnik AG

2016-06-14 – Chemnitzer Seminar

Medical Devices for the IoT – Design Challenges

Tilo Borchardt

Kardiologische Funktionsdiagnostik

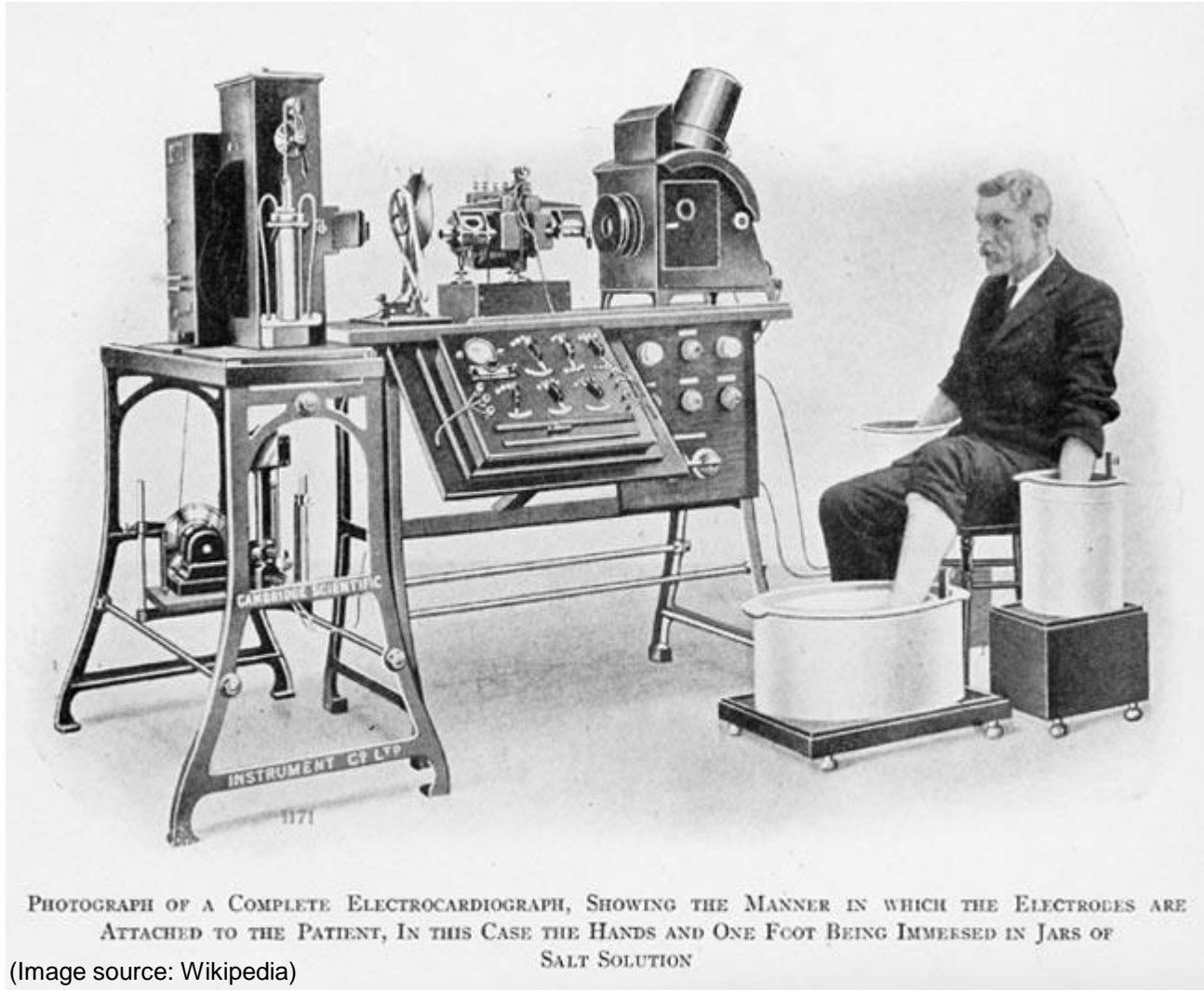


Vitalfunktions-Monitoring



Telemonitoring





Willem Einthoven

The clinical use of Einthoven's immobile equipment required transtelephonic transmission of the ECG from the physiology laboratory to the clinic about a mile away



(Image source: Wikipedia)



Norman J. Holter, ca. 1960

Portable device for continuous ECG recording on magnetic tape



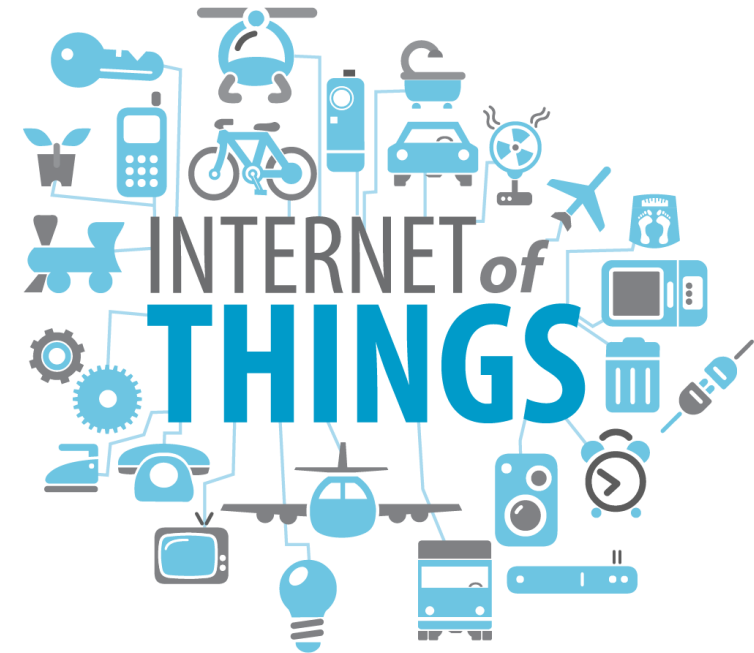
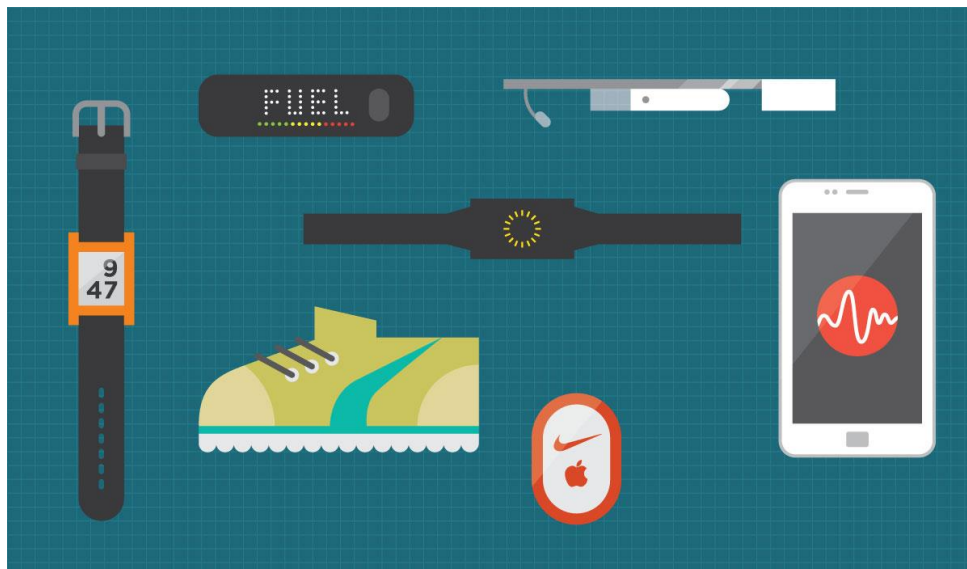
(Image source: GE Healthcare)

Holter ECG, 2012

Digital recorder with short range wireless transmission capabilities



- Miniaturisation
 - Wearable devices
 - IoT connectivity



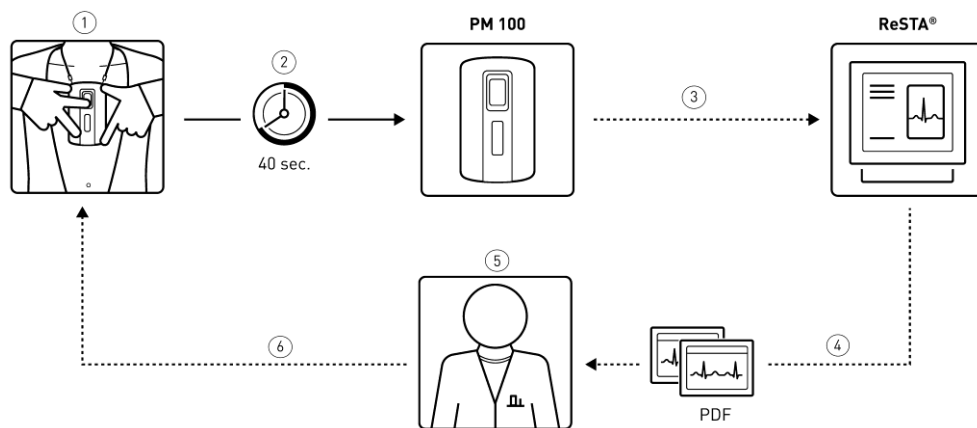


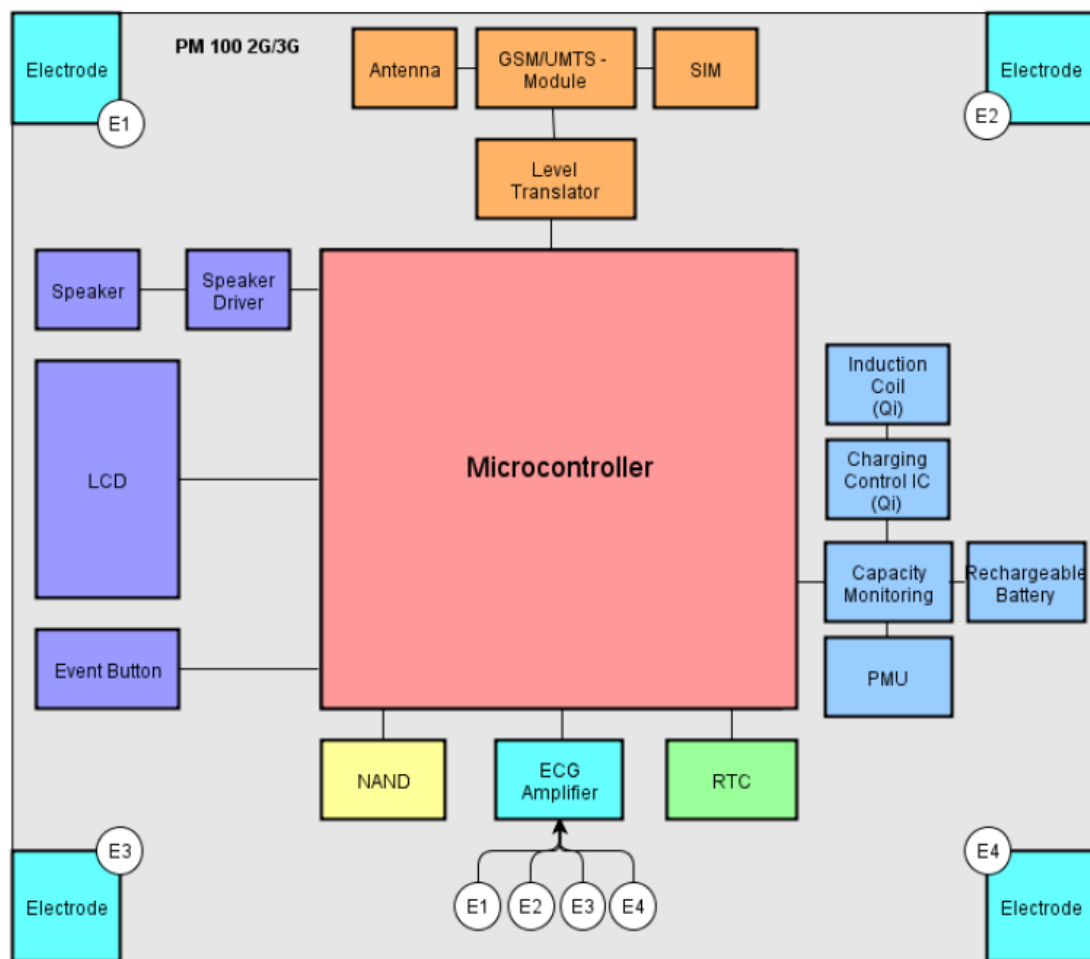
Ambulatory wireless ECG



GETEMED, 2013

Mobile ECG device for patient
activated ECG recordings, cellular
transmission capabilities







- Diagnostic purpose > *Medical Device Guidelines*
 - MDD, FDA, Health Canada, ...
 - Wireless communication capabilities > *Radio Equipment Guidelines*
 - R&TTE / RED, FCC, IC, ...
- Demonstration of conformity by compliance to international standards



Costs can easily exceed EUR 50.000



- Mechanical hazards
 - ...
- Chemical and biological hazards
 - ...
- Electromagnetic hazards
 - Electric shock e. g. by high currents
 - Burns e. g. by burning or exploding lithium battery
 - Electromagnetic radiation, e. g. disturbance of other medical equipment
 - Strong electromagnetic fields, e. g. corruption of signals and/or data
 - Electrostatic discharge, e. g. corruption of data
 -



➤ *Hazard mitigation by design*

➤ *Effectiveness of the mitigation has to be demonstrated by type approval test*

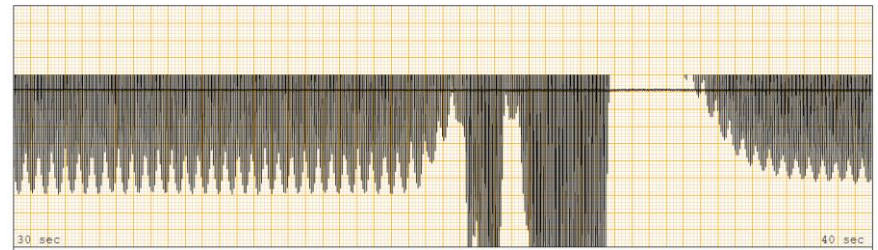


- Mix of signals
 - Low frequency analog 0,5 ... 40Hz (ECG)
 - High frequency 900/1800MHz (wireless technology)
 - Clock signal
 - Data signals
- Avoid disturbance of analog signals by digital signals

normal



disturbed





Intended radiation

Electrostatic discharge

Unwanted radiation that can disturb other devices in the environment

Device

Cellular

Radiated interference

Analog Input

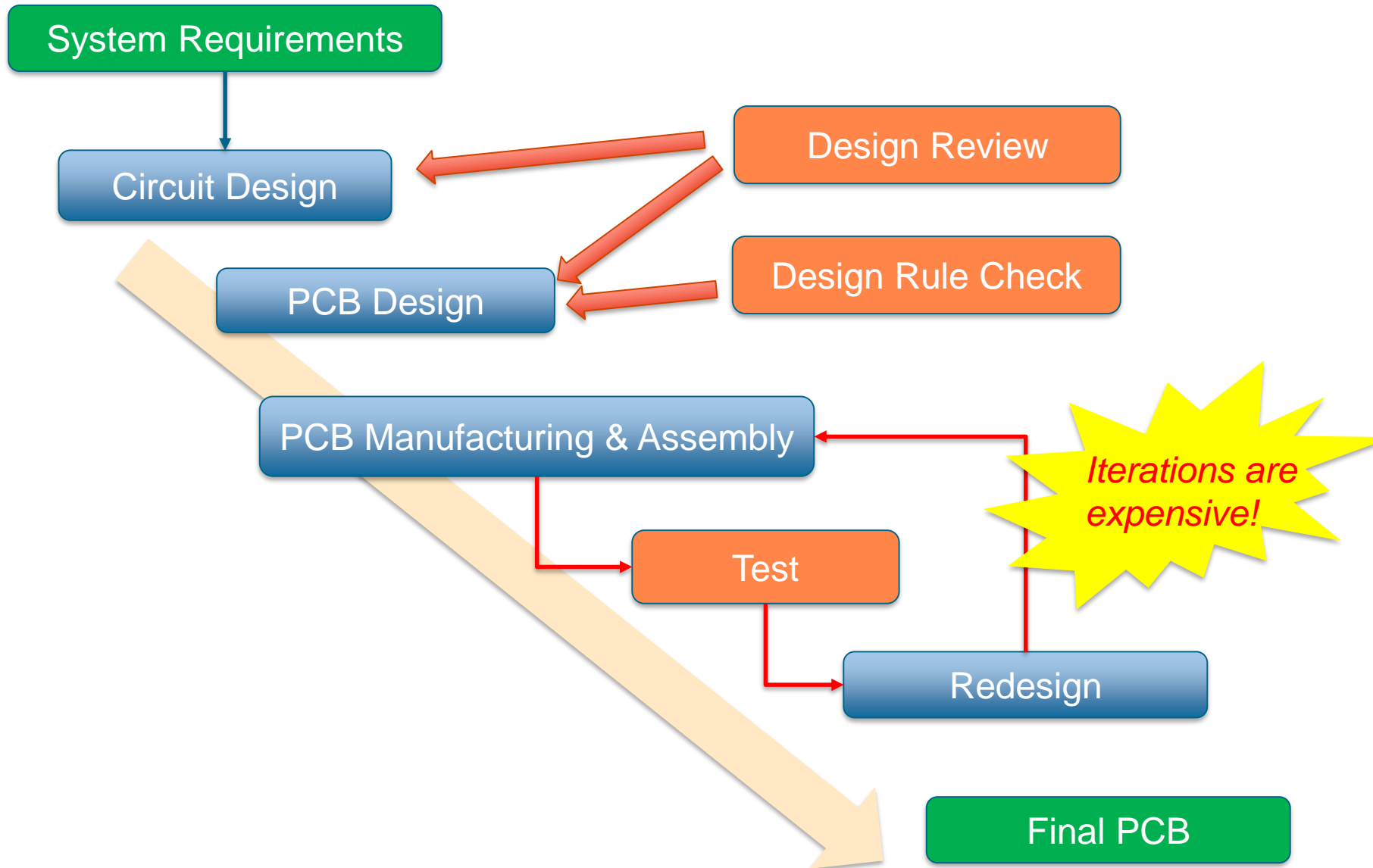
Digital

Power

Conducted interference

Unwanted radiation from environment

- Issues need to be addressed early in the design phase





- The PCB does not only carry and connect components
- The PCB is one of the most critical components
- Design failure can cause the final device not to work as intended or not to pass certification > device cannot be placed on the market

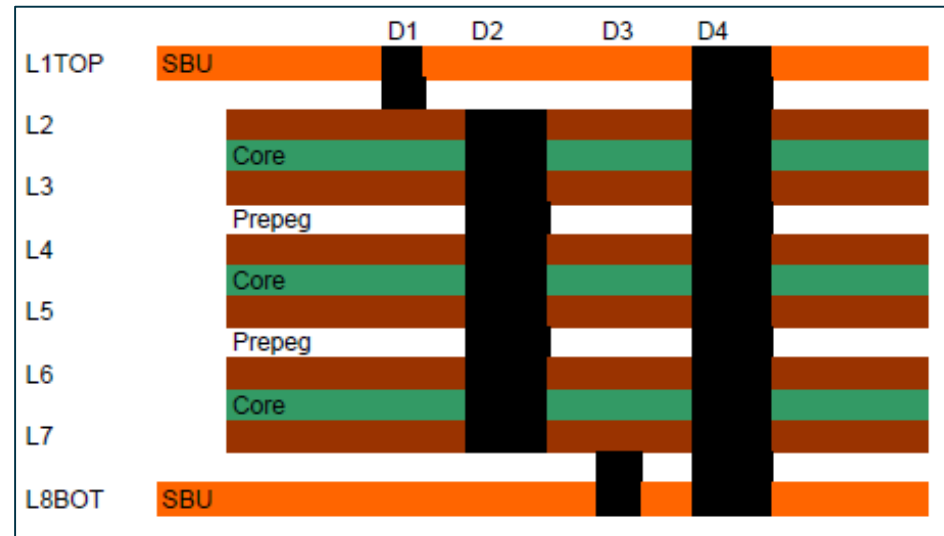
➤ Design rules for PCB design and design verification

- *Reviews*
- *Design rule checks*
- *Impedance control*





- Desired form factor and EMC performance could not be accomplished with standard PCB technology
- Solution: HDI / SBU technology for better routing options
 - + Better EMC performance
 - + Less space required
 - + Small PIN grid arrays possible
 - Higher costs

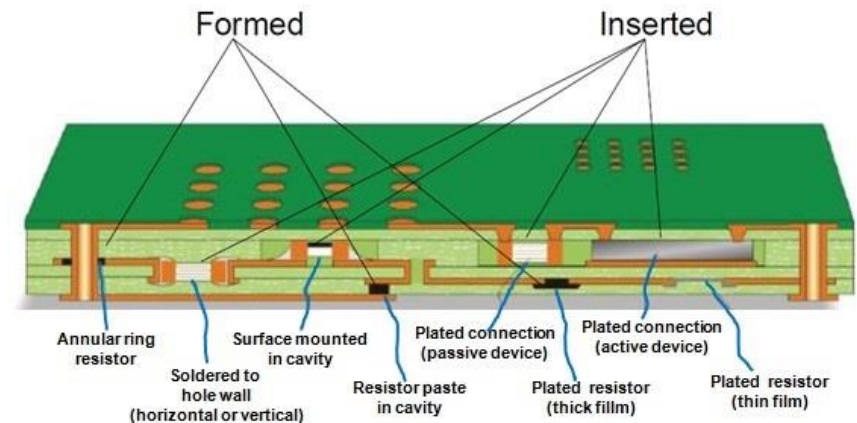




Demand for smaller devices requires the use of other technologies:

- Embedding components within the board substrate

Image source: electronicproducts.com



- Use of flexible PCB material



Image source: IMEC



Key facts

- Privately owned company, originally founded 1984 in Berlin, move to Teltow 1998
- Branch office in Chemnitz
- 70 full-time employees
- R&D, manufacturing, marketing & sales, service & QA

Approvals

- ISO 9001:2008 und ISO 13485:2012
- Approvals for USA (FDA), Canada (CMDCAS), Korea, China & Japan
- IHK certified to train apprentices

Recent Highlights

- 2010: RegioStars Award
- 2010: Visit Dr. Merkel at Medica
- 2011: Big Telemonitoring project
- 2012: Fontane project
- 2013: German Innovation Award



Thank you!



GETEMED
Medizin- und Informationstechnik AG
Oderstraße 77 / 14513 Teltow
Telefon: +49 3328 3942-0
Telefax: +49 3328 3942-99
info@getemed.de / www.getemed.de