Challenges in the Design of Integrated Circuits for Wireless Power Delivery and Information Transfer in Implantable Medical Applications

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Context

- Medical devices vs Semiconductors industries
- How to develop a medical instrument, equipment, or device
- Design considerations of a transceiver used for implemented medical device
- The possible application and research directions of the Wireless Transceiver
- Wireless Power Transfer for Miniaturized Medical Devices

Medical devices vs Semiconductors industries

Similar annual sales of top 20 companies, but different in ...
How to develop a medical instrument, equipment, or device

With the Integrated Circuit is Enabling Technology

What is a medical device

• An instrument, apparatus, implement, machine, contrivance, implanted in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  • Recognized in the official National Formulary
  • Intended for use in the diagnosis of disease or other conditions
  • Intended to affect the structure or any function of the body of man or other animals

Classification of medical Devices

• Class I: General controls
• Class II: General controls with special controls
  • infusion pumps, and surgical drapes…
• Class III: General controls and premarket approval
  • implantable pacemaker, pulse generators, automated external defibrillators…

Research and Development of an medical system

A Medical System with Portable and/or Implantable Medical Devices

Composition or Development Platform

• Communication protocols and modules
• information security
• Sensing modules
• Pacing modules
• Wireless battery recharge module
• Lead impedance measurement modules
• Accelerometer modules
• FW download module
• RTC module

( Terms and Definitions)
A Portable and/or Implantable Device

• Electronic implantable medical devices (IMD) are designed to be fully or partially implanted in the human bodies through surgeries[1], and remain in bodies for several hours to several years or even permanently after the surgical intervention.

What is a Portable and/or Implantable Medical Device?

Examples of Portable and/or Implantable Medical Devices

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Examples of Portable and/or Implantable Medical Devices

Enabling Technology is Integrated Circuit

• Information Sciences: Acquisition processing, Storage Transmission of (medical and life) signals

Well known implemented medical devices in clinical application

• cardiac pacemakers,
• implantable defibrillators,
• Cochlear implants,
• nerve stimulators (Functional Electrical Stimulation-FES),
• limb function stimulation,
• bladder stimulators,
• Sphincter stimulators,
• diaphragm stimulators,
• implantable infusion pumps,
• bio-monitoring devices such as the capsule endoscope.

About the information security - Mostly at the system level and implemented in software

About the information security - Mostly at the system level and implemented in software
Two options to power an implemented medical devices

- miniature battery, and wireless power.
- lowering the circuit power consumption,
- to evaluate the available space for power supply components inside IMSs,
- The lifetime and reliability requirement, before choosing the power type.
- For example, a cardiac pacemaker relying on a reliable energy source may choose a battery, while an intraocular IMD usually choose wireless power since there is no room for a battery. The requirements on the wireless transceivers for different IMSs are quite diverse, in terms of data rate, signal transmission distance, and communication directions (single direction or two-way). The data integrity and bit-error rate (BER) tolerance are also of great importance, and the poor performances on these aspects may lead to harmful and even fatal malfunction.

<table>
<thead>
<tr>
<th>IMSs</th>
<th>Power consumption</th>
<th>Target data rate</th>
<th>Life-Time</th>
<th>Energy Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomonitoring System</td>
<td>&lt;100 μW</td>
<td>&lt; 10 kb/s</td>
<td>a few days</td>
<td>Primary Battery</td>
</tr>
<tr>
<td>Capsule Endoscope</td>
<td>1–100 mW</td>
<td>&gt;100Kb/s</td>
<td>10 Years</td>
<td>Primary Battery</td>
</tr>
<tr>
<td>Cochlear Implant</td>
<td>10–100 W</td>
<td>NA</td>
<td>Inductive Power</td>
<td></td>
</tr>
<tr>
<td>Cardiac Pacemaker</td>
<td>10–100 W</td>
<td>&gt;1 Mb/s</td>
<td>10 Years</td>
<td>Primary Battery</td>
</tr>
<tr>
<td>Cochlear Implant</td>
<td>10–100 W</td>
<td>NA</td>
<td>Inductive Power</td>
<td></td>
</tr>
<tr>
<td>Hearing Aid</td>
<td>300–2000 mW</td>
<td>200 mW</td>
<td>1 Week</td>
<td>Rechargeable Battery</td>
</tr>
<tr>
<td>Retinal Implant</td>
<td>40–200 mW</td>
<td>&gt;100 mW</td>
<td>NA</td>
<td>Inductive Power</td>
</tr>
<tr>
<td>Neural Recorder/Stimulator</td>
<td>1–100 mW</td>
<td>NA</td>
<td>Inductive Power</td>
<td></td>
</tr>
<tr>
<td>Artificial Heart</td>
<td>1–10 mW</td>
<td>NA</td>
<td>Inductive Power</td>
<td></td>
</tr>
</tbody>
</table>

Frequency band selection for implemented medical devices transceiver design

- considering the huge variation of EM signal propagation characteristics through human tissues with different frequencies. Based on FCC frequency regulations, the MedRadio band (composed of several incoherent bands in 400–457 MHz) has superior propagation characteristics for implants, quiet channel properties, and worldwide availability, which are the primary reasons for its popularity for implant applications. The 2.4 GHz ISM band, with the mature circuit technologies, wide support for connecting to smart phones and other mobile devices, convenient access to the network, is also widely used for implantable medical systems.

<table>
<thead>
<tr>
<th>Global Frequency</th>
<th>Category</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 – 315 kHz</td>
<td>EU medical implant</td>
<td>Not allocated outside EU</td>
</tr>
<tr>
<td>13.56 MHz</td>
<td>ISM</td>
<td>Ranges up to 7 MHz</td>
</tr>
<tr>
<td>5.8 GHz ISM</td>
<td>802.11a</td>
<td>Ranges up to 7 MHz</td>
</tr>
</tbody>
</table>

IMD antenna design for IMSs

- IMD antenna design is also very challenging due to the size and shape restrictions, and the complicated working environment in human bodies. Since the electrical properties of the human tissues varies a lot with the patients’ weight, age, posture changes, etc., the IMD antennas may adopt different sizes and shapes depending on the implantation location, which further limits the freedom of the designer.

Implemented Transceivers for IMD

- 400 MHz RF transceiver
- 2.4 GHz RF transceiver
- Reconfigurable Sliding-Intermediate-Frequency (IF) Transceiver for 400 MHz/2.4 GHz IEEE 802.15.6/ZigBee
- 400 MHz/2.4 GHz TRX for dual-band communication

Asymmetrical RF Transceiver in 400MHz Band

- The data transmission from IMD to EHD sometimes requires very high burst data rate, while the control/command information receiving requires much lower data rate
- Asymmetrical wireless transceiver for IMD
  - High speed transmitter, very careful low power design
  - Low speed receiver
  - TX: 3Mbps MSK modulation
  - High data rate → low duty cycle for battery
  - MSK chosen for bandwidth, performance & circuit complex.
  - RX: 64kbps OOK demodulation
  - Low circuit complexity
A 400MHz IMD Transceiver

Low Power Transmitter with Current Sharing

- Zero-IF MSK modulator
- DC current sharing between IF DAC and mixer
- Traditionally mixer and IF DAC are cascaded
- No traditional power amplifier
- Mixer directly loaded by antenna

Frequency Synthesizer w/ Current Reuse

- 800M LC VCO w/self calibration on tuning range
- Double as the carrier frequency to generate quadrature carriers
- Current Reuse between VCO & Quadrature frequency divider [1]
- Current budget: VCO 0.6mA, all other blocks 0.2mA

Antenna Design for IMD Transceiver

- Difficult to achieve good antenna matching for implantable SID with traditional antenna
- Surrounding environment affects the antenna characteristic a lot
- Difficult to characterize antenna's surrounding environment
- In this design, an inductor serves as antenna
  - $C_{\text{tune}}$ is calibrated so that the RF port achieves resonance
  - Is no traditional antenna, therefore no traditional antenna matching
  - A virtual transformer works as antenna
  - Inductor $L_{\text{emit}}$ serves as the primary coil
  - Human body serves as the secondary coil
  - The transformer has very low coupling
  - The transmitting loss is high (negative)
  - Our experience: if inductor $L_{\text{emit}}$ has an RF ac current of 10mA (peak to peak), PBS receiving antenna can receive > 75dBm RF signal from outside body

Switch between RX & TX

- RF I/O port is calibrated for resonance at TX mode
- A RF peak detector is used to set the tuning capacitor such that to have highest RF output at the RF I/O port
- At RX mode, the load (inductor) will see different capacitance from TX mode
- Transistors working regions change a lot as parasitic capacitance changes a lot
- The dummy circuits in the center of this figure is toggled to compensate for the capacitance difference
- The dummy circuit is a duplicate of the transistors connected to RF I/O port

Media Access Controller (MAC)
400 MHz Transceiver for IMD's

<table>
<thead>
<tr>
<th>Parameters</th>
<th>This work</th>
<th>ISSCC 2012</th>
<th>JSSC 2017</th>
<th>TCAS-I 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMOS Process</td>
<td>180 nm</td>
<td>90 nm</td>
<td>28 nm</td>
<td>90 nm</td>
</tr>
<tr>
<td>Supply voltage/V</td>
<td>1.2</td>
<td>1.2</td>
<td>0.5/1</td>
<td>1.1</td>
</tr>
<tr>
<td>Modulation</td>
<td>64-QAM</td>
<td>HS-OQPSK</td>
<td>GFSK</td>
<td>OOK</td>
</tr>
<tr>
<td>Carrier Frequency/GHz</td>
<td>2.4</td>
<td>2.4</td>
<td>2.4</td>
<td>2.4</td>
</tr>
<tr>
<td>Data Rate/Mbps</td>
<td>20</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>EVM/%</td>
<td>11</td>
<td>2.3</td>
<td>--</td>
<td>5.5</td>
</tr>
<tr>
<td>Power Consumption/mW</td>
<td>2.37</td>
<td>5.4</td>
<td>3.7</td>
<td>2.17</td>
</tr>
<tr>
<td>Power Efficiency</td>
<td>120 pJ/bit</td>
<td>1.10 nJ/bit</td>
<td>1.14 nJ/bit</td>
<td>2.17 nJ/bit</td>
</tr>
<tr>
<td>TX Pout/dBm</td>
<td>-15</td>
<td>-1</td>
<td>0</td>
<td>-10</td>
</tr>
</tbody>
</table>

H. Song et al., “A SoC with 0.18 μm CMOS 400 MHz Transceiver and 3.3 μV MCU for implantable endoscope with bidirectional communication,” in Proc. ISSCC, San Francisco, CA, 2012, pp. 1–4.


2.4 GHz IMD Transceiver

<table>
<thead>
<tr>
<th>2.4 GHz Transceiver for IMD’s</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 400 MHz wireless transmitter in 0.38 μm CMOS process</td>
</tr>
<tr>
<td>• Low duty cycle ratio</td>
</tr>
<tr>
<td>• Reduced average power consumption (average 27 μW)</td>
</tr>
<tr>
<td>• 3 Mbps MSK modulation</td>
</tr>
<tr>
<td>• Carrier frequency 416 MHz</td>
</tr>
<tr>
<td>• Peak current 2.7 mA</td>
</tr>
<tr>
<td>• Turned on for 14 ms every second</td>
</tr>
<tr>
<td>• Sampling rate = 1 sps</td>
</tr>
</tbody>
</table>


Implementation of PA network

• An embedded 16-order FIR filter (for OOB noise attenuated by at least 20 dB)
• 16 digitally controlled class-AB PA cells with each IQ path
• The cascode transistors as the switches of the PA cells to avoid voltage breakdown issue.
• Each PA cell: two pseudo-differential amplifiers controlled by two internal signals EN1 and EN2


Realization of the FIR filtering using Digital Power Amp. and shift register


Reconfigurable Sliding-IF Transceiver for 400 MHz/2.4 GHz IEEE 802.15.6/ZigBee for IMDs

Wideband RF Front-end and off-chip matching circuits

- Active shunt feedback LNA with multiple gm enhancement
- M7/8 provides gm
- M5/6 feedback for wideband matching
- M7/8 wide bias range
- Class AB/B/C reconfigurable PA
- Conduction angle adjustable
- DBPSK/DQPSK-class AB
- OQPSK/MSK-class B/C
- Matching circuits shared by TX/RX
- An off-chip 1.5 balun needed
- Reasonable input impedance <350 Ω to flatten the input reflection
- Optimum load 320 Ω
- External 2nd order LC filter suppressing 1.4~1.5 GHz

Reconfigurable RX Mixer

AGC flow
1. Set maximum RF gain
2. Turn VA1 to 30~60mV
3. Pre-determine IF gain
4. Adjust IF gain by N dB according to interference magnitude of VA2
5. Check ADC output and adjust VA3 to 200~600mV

Automatic gain control (AGC) method


TX up-converter with PPF IQ/LO generator

- A second order PPF
- generate the IQ Local Osc. signals for the HF mixer.
- The Poly Phase Filter order and RC values
  - trade-off: image rejection ratio VS LO driver power consumption
  - An inductor resonate S with the PPF equivalent capacitor
  - deliver large amplitude IQ LO signals to the HF mixer.
- LC tank
- load filter out 1.4~1.5 GHz IM signal

Reconfigurable Sliding-IF Transceiver IMDs

400 MHz/2.4 GHz TRX for dual-band communication


Signal levels and Harmonic Suppression

Interference Cancellation

2.4 GHz band RX RF frontend and analog baseband circuit design

RF frontend
- Single-ended cascade LNA
- Passive quadrature mixer
1st mixer
- I/Q signal frequency: 4/5 of the desired carrier frequency

2nd mixer: 1/5 of the desired carrier frequency
- I/Q branches
- 2nd mixer: 1/5 of the desired carrier frequency
- Quadrature analog baseband circuits
- 3-programmable-gain amplifier
- Active-IC 3rd-order Bessel/Butter
- 8-bit SAR ADC with programmable-sampling rate up to 80 Msps

Frequency Synthesizer for 2.4 GHz

A 1.9-2.5 GHz semi-digital Δ-Σ PLL
- Bang-bang phase detector (BBPD) loop
  ○ Decreases the integration capacitor
  ○ Generates 6-bit digital input bits
- The VCO
  ○ The analog input VC by PLL
  ○ 40 MHz/V VCO gain

400 MHz TRX Design

The 400 MHz TX
- 350-500 MHz ring VCO based fractional-N PLL synthesizer
- Digital intensive modulator
- Inverter-based phase selector
- Shaping filter suit for low-power design
- PA
400 MHz TRX Design


The 400 MHz RX
- Single-end LNA
- Passive quadrature mixer
- Analog baseband
- 3 PGAs: 4 parallel units, 3 of them can be shut down
- 3rd order LPF (bandwidth programmable between 1.2–5 MHz)
- DC offset calibration (DCOC) and automatic gain control (AGC) circuits

2.4 GHz/400 MHz Dual-band TRX for IMD’s


The possible application and research directions of the Wireless Transceiver

Case studies

Assuming that we have this transceiver, what can we do to use it for a medical devices?

Wireless transceiver
- Proprietary Design
- 400 MHz
- 3 Mbps

Capsule endoscope
- Image Sensor
- 2 frames/s
- 240x240

Making into Products & Commercialization
- Spin-off company
- CFDA
Implantable Intracranial Pressure (ICP) Sensing

- Reduced risk of infection
- No constraint on patient's movement
- No CSF drainage

- Implantable ICP Device + Wireless Data Recorder + Computer
- Wireless data link: 416 MHz

Electronics in the ICP

- The ICP device is composed of an air pressure sensor & a System-on-a-Chip (SoC)
- The SoC has the following function blocks:
  - Sensor interface
  - Working flow controller
  - 400 MHz wireless transmitter
  - Power management
  - Wakeup controller
  - Clock generator, voltage reference, etc.

Proposed Implantable ICP Device

- Two air pouches:
  - Pressure sensing pouch
  - Air reservoir pouch
- No contact between CSF and sensor—good biocompatibility
- No CSF in the tube

Balance measuring device for total knee replacement operation

- Range image enhancement under the conditions of small objective distance, ultra-large or small illuminance with high dynamic range

Balance measuring device for hip replacement surgery

- Implantable ICP Device + Wireless Data Recorder + Computer
- Wireless data link: 416 MHz
ICP SoC Implementation Result

**SoC Performance SUMMARY**

<table>
<thead>
<tr>
<th>Technology</th>
<th>µm 0.18</th>
<th>1P6M CMOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply Voltage</td>
<td>3V</td>
<td>button batteries</td>
</tr>
<tr>
<td>Off-chip components</td>
<td>6 off</td>
<td>chip capacitors</td>
</tr>
<tr>
<td>Clock frequency</td>
<td>24MHz</td>
<td></td>
</tr>
<tr>
<td>Logic gates</td>
<td>145k</td>
<td></td>
</tr>
<tr>
<td>Current consumption (communication idle)</td>
<td>240 µA</td>
<td></td>
</tr>
<tr>
<td>Average power (1 sample/second)</td>
<td>260 µA</td>
<td></td>
</tr>
</tbody>
</table>

Prototype System of Implantable ICP Sensing

Implantable ECG monitoring system

- **Implantable ECG monitor**
  - **Advantages:**
    - Easy for implant operation
    - Small and single incision, subcutaneous insertion
    - Long-term continuous low-noise monitoring
    - Automatic abnormal ECG identification
    - Recording in certain point
  - **Patient/APP**
    - Upload data
    - Start recording while feeling sick
  - **Doctor/APP**
    - ECG data download and analysis
    - Decide parameters for ICM algorithm

Prototype Implantable ECG monitoring system

- **Circuit**
  - 400 M TRX chip
  - Commercial chips
- **ICM prototype**
- **PC software**
  - Configure & display
- **Wireless NFC r/w device**

Wireless Power Transfer for Miniaturized Medical Devices
Wireless power transfer (WPT)

- Advantages
  - Contactless, convenient to use
  - Waterproof, readily used in adverse conditions
  - Safe, easy to power implant and movable devices...

WPT timeline

- 1891: Microwave-powered airplane
- 1961: First WPT across biological tissue
- 1969: WPT system for moving vehicles
- 1978: WPT for home appliances
- 1980s: MIT lighted up a 60W bulb
- 2007: Consumer elec. Market booms
- 2010s: Two organizations proposed Standards

Main WPT mechanism

- A typical WPT system is mainly composed of transmitter, power link and receiver

WPT for miniaturized medical devices

- Classified by clinical application
  - Diagnostic Instrument (DI)
  - Treatment Instrument (TI)
  - Auxiliary Instrument (AI)

WPT architecture

- 4 basic compensation arrangements for resonance: SS, SP, PS, PP
- Variables in power link
  - Coupling factor (k) variations resulting from variable link distance, link misalignment and orientation angle, etc.
  - Effective resistance (R_{Leff}) variations resulting from loading, receiver efficiency and topology, etc.

Power link

- Link efficiency \( r_{link} \) depends on k and \( R_{Leff} \) and only peaks when \( k \) and \( R_{Leff} \) match with each other
Multiple coils technique

- Include: primary coil(L1) – primary resonator(L2) – secondary coil(L3) – secondary resonator(L4)
- Novel primary multi-resonator coil design
  - all L2s have strong coupling with L1 by fully overlapping
  - one or more resonators that are best coupled with the Rx (where the resonator(s) that transfer power) are chosen
  - obviate the need for a tracking system or switching the coils

Receiver design

- Typical circuit: rectifier + regulator + load
- The load can be modeled as resistor with filtering capacitor, current source, or battery
- Coupling factor and load variations will affect output voltage
- Objectives: output voltage regulation and high efficiency
  - Transmitter-side controls
  - Receiver-side controls
  - Merge several stages into one stage, etc.

Transmitter design

- Typical circuit: power source + power amplifier
- Pay attention to basic connection of power source
  - Class-D PA is widely used. Carefully design the switch control timing for high transmitter efficiency
-系統設計

- Cyclic operation in RX compares output voltage with a reference voltage, and the result is fed back to TX
- In TX, based on the feedback info, PA’s switching frequency is controlled as \( f_{\text{sys}} \) or \( f_{\text{sys}}/2 \) to deliver different power level
- Output voltage is regulated with the system control

Sub-Harmonic Resonant Switching

- The hysteretic comparator in RX compares output voltage with a reference voltage, and the result is fed back to TX
- In TX, based on the feedback info, PA’s switching frequency is controlled as \( f_{\text{sys}} \) or \( f_{\text{sys}}/2 \) to deliver different power level
- Output voltage is regulated with the system control

Typical circuit: power source + power amplifier
- Class-D PA is widely used. Carefully design the switch control timing for high transmitter efficiency
Reconfigurable Rectifier for SP compensation

- Two modes: full-bridge rectifier in 1X mode and voltage doubler in 2X mode
- Local PWM loop in RX controls duty cycle of mode-switching of the rectifier between 1X and 2X
- Suitable for Series-Parallel compensation

Local control for range extension

- In order to extend the regulatable region, local control was proposed
  - Obtain the mode info in RX and send it back to TX via additional detection coil
  - Adjust the transmitter power in TX based on detected info
- Two novel backscattering uplink techniques were proposed

Suitable for Series-Parallel compensation

reconfigurable Rectifier for SS compensation

- Three modes: full-bridge rectifier in 1X mode, half-bridge rectifier in ½X mode and no current to load in 0X mode
- Local PWM loop in RX controls duty cycle of mode-switching of the rectifier between 3 modes
- Suitable for Series-Series compensation

Output voltage ripple reduction

- Based on reconfigurable Rectifier with 1X/½X/0X modes switching
- Reduce the limit cycle oscillation effect
  - Output voltage ripple is reduced
- New switching synchronization method
  - Only one switching edge needs synchronization
  - Realized with a shift circuit

Global control for range extension

- In order to extend the regulatable region, global control was proposed
  - Obtain the mode info in RX and send it back to TX via additional detection coil
  - Adjust the transmitter power in TX based on detected info
- Two novel backscattering uplink techniques were proposed

Suitable for Series-Series compensation

Capsule Endoscopy

- To diagnose gastrointestinal conditions without the need for any sedation
- Advantages: easily swallowed, painless, no harmful radiation, etc.
- Our achievements by Tsinghua group
  - Digital IC design techniques
  - Image enhancement technique
  - Transceiver design techniques
  - Wireless powering techniques
  - Have been applied into industrial production

Digital IC design

- Achieved low-power[1]
  - Multi-stage clock management
  - Stop-starting techniques
  - New image compression algorithm
  - 8 frames/s, 320*288 pixels, 2MB/s, 6.2mW
- Multiple Cameras for miss rate reduction[2]
  - Master-slave architecture with efficient bus design and 4-level clock management
  - Movement sensitive control and camera selection

References:
Multiple receiving coils

- Proposed a power harvest circuit
  - Combine power from three orthogonal receiving coils
  - Derived theoretical expression for the power flow from the transmitter
  - Verified the power combination mechanism
  - Contains three rectifiers and one output capacitor

Wireless charging

- Proposed a wireless charging unit
  - Consisting of a rectifier and a lithium-ion battery charger
  - Designed a dynamic offset-controlled comparator to attenuate multiple pulse
  - Proposed a mode-division control method to realize smooth CC to CV transition
  - Use a state-checking operation to ensure the security

Hearing aids

- Approximately 360 million people in the world live with a debilitating hearing loss
- Our group proposed a smart binaural hearing aid system
  - Apply advanced binaural DSP algorithms to the acoustic signals received from both ears
  - Contains a low-power low-delay radio transceiver
  - Real-time DSP software analyzes 4-channel audio signals simultaneously

Power management unit for hearing aids

- Wirelessly charge the built-in rechargeable batteries and generate voltage for hearing aid devices
- Include a charger communication interface (CCI) to provide the battery charging info for user interaction
- Rectifier control technique and charging algorithm were proposed for high efficiency

Simultaneous power and data transfer

- Several methods for simultaneous power and data transfer
  - RFID: low power level
  - Via extra WiFi or Bluetooth: high cost
  - Through common coil path: pay attention to the crosstalk
- Our group has proposed a new data modulation method in which power and data transfer simultaneously through the common coil path with small crosstalk
Conclusion

The requirements of application are the source of innovation.
Long time persistence is the key fact of success.

A picture used by Chris Cloninger (Analog Devices Inc.) in a talk in Tsinghua University, 2008.