Technology Challenges for Active Cardiac Implantable Devices

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Heart rhythm disorders and associated therapy devices

Bradycardia
- Pacemaker

Atrial Arrhythmias
- Pacemaker

Ventricular arrhythmias
- ICD

Congestive Heart Failure
- CRT-D
Smart, Powerful, Small

CRT-D

Heart Failure
- 2007: M€ 7,629
- 2012: M€ 10,573

Tachycardia
- 2007: 2,761
- 2012: 4,372

Bradycardia
- 2007: 2,844
- 2012: 2,890

CAGR, 2004-09 (%)
- CRT-D: 11.5%
- ICD: 9.6%
- CRT-P: 0.2%
- PM: 6.7%

Total: 6.7%
Active Cardiac Implantable Devices

- RF communication
- Low power CPU
- Analog sensing & pacing
- RAM
- ROM
- High voltage Defibrillation
- Titanium package
- Hermetic package
- MEMS Sensors
- Programming System
- Wireless Remote Monitoring
Requirements for an implantable sensor

Physiologic but simple

Miniature

Integration

Low current consumption

Reliable → Hermetically sealed

Biocompatible

Leadless / Wireless
1D Accelerometer
What's inside the package?

Feedthrough with ground wire and capacitor filters

Hybrid circuit encompasses only components automatically managed by "Pick & Place" machine

Flex circuit provide high density interconnection and cancels complex & risky feedthrough wire bending
What’s inside? Hybrid circuit
Shock circuits
What’s inside? Ovatio defibrillator
Defibrillator downsizing

![Graph showing defibrillator downsizing over time.](image)

- **VVI**
- **DDD**

**Components:**
- Mechanics & interconnexion
- Connector
- Electronics
- Capacitors
- Battery

Years: 1993 to 2003

Volumes: 78 cc, 49 cc, 39 cc, 29 cc
PoP and WDoD package
A technical challenge in CRM: circuit & package miniaturization

Innovations from: IPEDIA
Integration of passive components in silicon

Adapted from NXP
Hybrid Platform

Detailed views of DIAMOND stack process
Heart failure

2005: up to 14 million Europeans currently suffer from heart failure.

2020: increasing to 30 million.

Over 3.6 million new cases of heart failure are reported each year in Europe.

First cause of cardiovascular mortality in Europe.

Heart Failure is the most common cause of hospital admission in people over 65.
Optimal Management of Heart Failure

HF heart status change over time

- CRT settings must be repeatedly tailored to the individual patient

Self-adjustment of CRT parameters

- Cardiac resynchronization is permanently tailored to the patient
- Replaces time-consuming echocardiographic assessment required with conventional CRT devices require

Monitoring of the patient’s status
Heart failure sensor

Lead body (length=60cm)

Distal End, with accelerometer inside

Proximal end; connector fits into pacemaker receptacle

Pacing Tip

Lead Connections
Capteur SonR
What does the signal look like?
Clinical Efficacy of CRT continuous optimization with SonR versus standard clinical practice.

Clear
SonR sensor based optimization

% of population

<table>
<thead>
<tr>
<th></th>
<th>Improved</th>
<th>Non Responder</th>
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<tbody>
<tr>
<td>SonR Control</td>
<td>86%</td>
<td>14%</td>
</tr>
<tr>
<td>Control</td>
<td>62%</td>
<td>38%</td>
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</tbody>
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p=0.0013

L. Padeletti et al

Clinical Efficacy of CRT continuous optimization with SonR versus standard clinical practice.

Heart Rhythm 2010;7(5s):AB27_4
The future: exercise adaptive & monitoring of resynchronization

RA lead
RV lead
LV lead

CRT / CRT-D Device

Pulse Generator, Sense Amps

Micro-controller

Neuronal Co-Processor

Hemodynamic sensors

Real time AV and VV intervals optimization during exercise
Monitoring of implanted patients for detection of Cardiac Decompensation (early detection of pulmonary oedema condition)
Ventilation measurement

\[ \Delta Z = \Delta V/I \quad \text{and} \quad VE = k \cdot \Delta Z \]

Bonnet JL, Ritter P, Pioger G et al. Measurement of minute ventilation with different DDDR pacemaker electrode configurations
Pacing And Clinical Electrophysiol 1998; 21 ; 1 [Pt I] : 4-10
Clinical case: True positive

Patient hospitalized for CHF at the end of the 3-month FU phase D88). An alarm was delivered 1 month before at D58.
CRT system with multielectrodes lead

Multiple distributed & communicating hemodynamic sensors for diagnosis and treatment of HF
Biocompatible packaging with ASIC substrate and sensor
Evolution of implanted devices

FROM

A device with one, simple sensor on one lead

TO

A device with
- multiple, complex sensors
- multiple, complex actuators
- wired and wireless
RESEARCH in FP7: Leadless pacemaker

Diameter: 6 mm
Length: 26 mm
Leadless pacing system
RESEARCH in FP7: Leadless pacemaker

24mm*15mm*5mm

8 cc

1CC
Remote Follow-up of implanted Cardiac active devices

Telemedecine ... was born a long time ago!
Sorin remote monitoring: a global solution
Smart miniature low-power wireless microsystem for Body Area Networks

WiserBAN microsystem

RF & DSP SoC

65nm CMOS

RF & LF MEMS

Heterogenous SiP

2.4GHz mW-level <4x4x1 mm³

WiserBAN

RF+IF+LF MEMS

Miniature antenna

Hearing aids
Cardiac implants
Cochlear implants
Insulin pumps
Smart Systems for CRM
What do we need?

Ultra miniature micro-systems including

- High density sub micron technology chips.
- Large capacity static RAM
- Sensors: accélérometers, pressure, impédance to measure activity, workload position, contractility, volume, minute-ventilation, left side pressures etc...
- RF transmission: antennas, Baw filters, RF Mems for switches or sensors.
- HV switches and storage capacitors.
- Low leakage Hi energy density battery, efficient energy scavengers
- Micro-encapsulation, micro-connectors
- Low current consumption

Reliability and Biocompatibility: Blood tightness.
THANK YOU FOR YOUR ATTENTION
Biocompatible packaging with glass substrate

- **ENCAPSULATION STEPS**

(1): silicon case cover
(2): gold connection pad
(3): borosilicate substrate
(4): cavity for the ASIC
(5): ASIC de-multiplexers integration
(6): gold interconnections