RF Integrated Circuits for Medical Implants:

Meeting the Challenge of Ultra Low-Power Communication

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Outline

– The MICS Band

– Applications for Medical Devices

– Ultra Low-Power (ULP) Design Challenges

– Design Solutions

– Design Examples

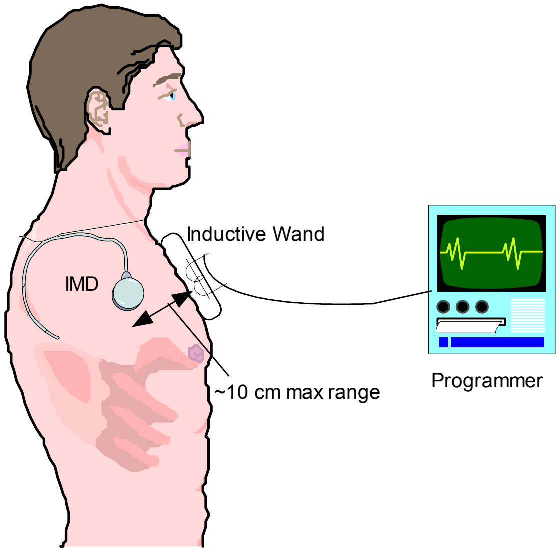
ZL70100: The Implantable Transceiver

ZL70081: The Swallowable Camera Pill Transmitter

ZL70262: ULP Audio Transmitter (Hearing Aids)

– Conclusion

History – Implanted Medical Telemetry



- 1980s – Inductive Telemetry
  - Near field (sub 1 MHz) at data rates <50 kHz
  - Low power (<1 mA)
  - Pick up in implant using small coil
  - Very short range (10 cm max) requiring close skin contact
- 1999 – RF Telemetry
  - Medical Implant Communication Service (MICS) Band
  - 402-405 MHz frequency allocation
  - FCC was petitioned in mid–1990s, spectrum allocated in 1999
  - 2003 Biotronik release MICS device (non-compliant)
  - 2004 Medtronic release MICS device
  - 2005 Guidant release ISM band (915 MHz) device
  - ISM bands (13.56, 433, 868, 915 MHz) are sometimes used
- 2002 - Ultrasonic Telemetry

The MICS Band

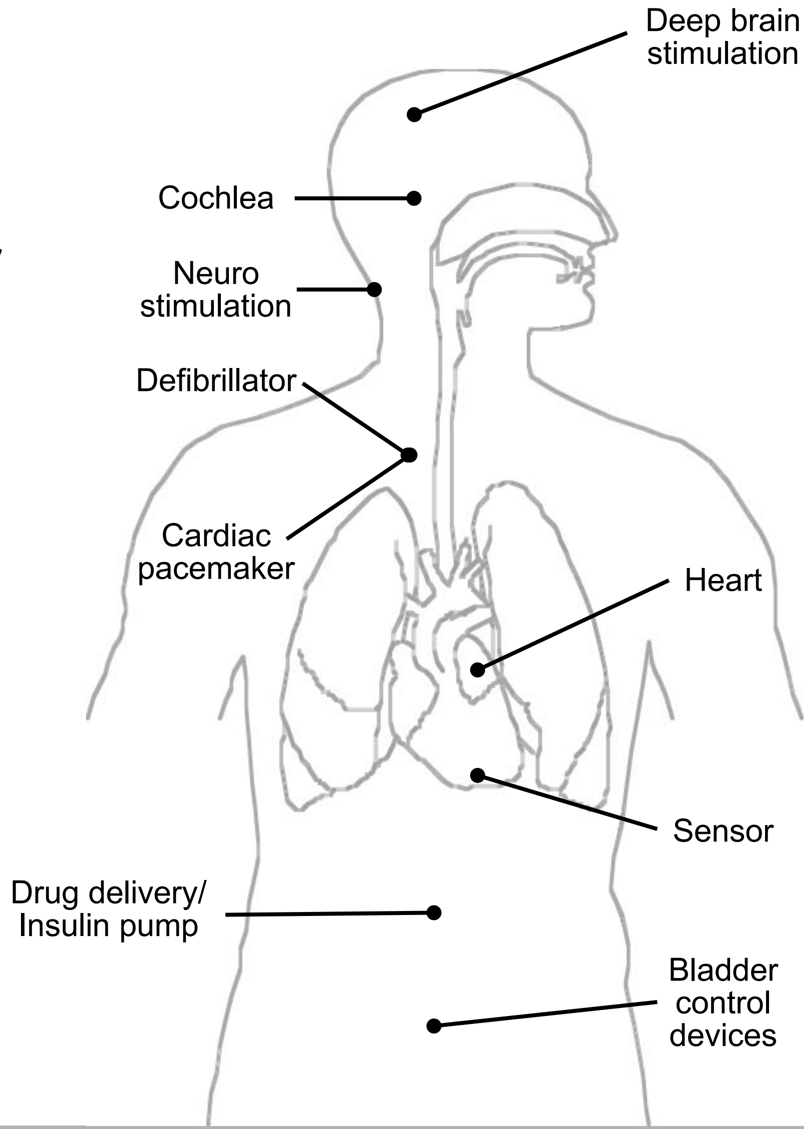
- **Medical Implant Communication Service (MICS)**
  - **402-405 MHz frequency allocation**
    FCC was petitioned in mid-1990s, allocated in 1999
  - **Short-range, wireless link to connect low-power implanted medical devices with monitoring and control equipment**
    Implanted Medical Devices (IMD) such as cardiac pacemakers, implantable cardioverter defibrillator (ICD), neurostimulators, etc.
  - **Why introduce MICS ?**
    - Removes limitations associated with existing short range inductive links (low data rate, very short range requires body contact)
    - Opportunity for improved healthcare and new applications
  - **Why 402-405 MHz?**
    - Reasonable signal propagation characteristics in the human body
    - Compatibility with incumbent users of the band (e.g. weather balloons)
    - General world-wide acceptance (US, Europe, Japan, Australia etc)

Why was MICS Introduced?

- Need for higher data rates
  - To upload patient events captured in the IMD's memory to the base station for analysis
  - Shorten doctor/patient consultancy times
- Need for longer range
  - Simplify home-monitoring for elderly
  - Locate the base station (programmer) outside of the sterile field during surgery
  - Broaden possible applications:
    Bedside monitor for emergency
- Competitive pressure of medical device industry
  - Higher data rates enable new, value-added services

MICS Applications

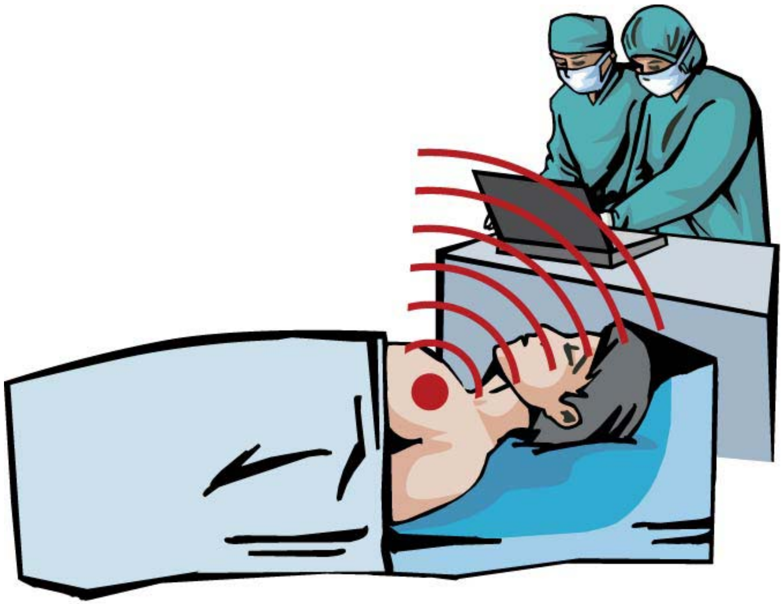
- Stimulatory Devices
  – Pacemaker
  – Implantable Cardioverter/Defibrillator (ICD)
  – Neurostimulators and pain suppression devices
  – Cochlea implants/hearing aids
- Measurement/Control/Other Devices
  – Drug infusion and dispensing
  – Artificial heart and heart assist devices
  – Implanted sensors
  – Control of other artificial organs and implanted devices



MICS Benefits – Operating Room

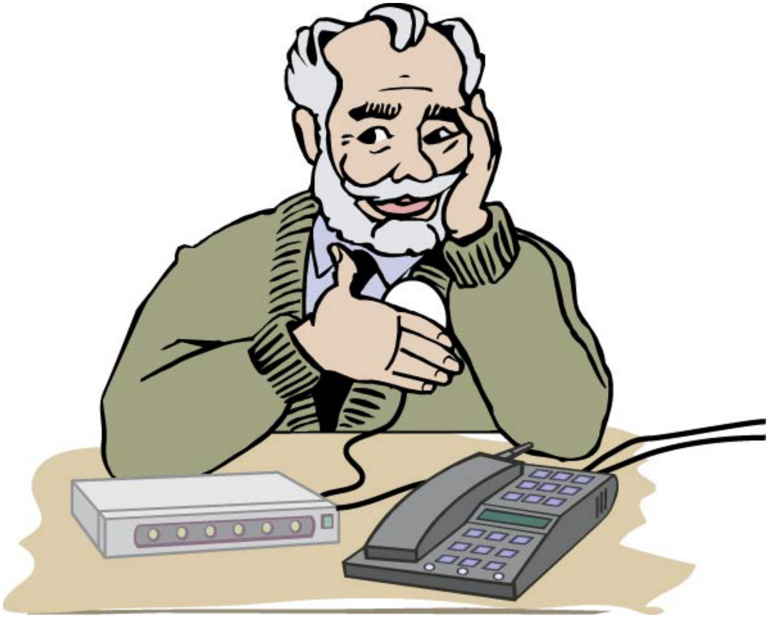
Today

Future with MICS



MICS Benefits – Home Monitoring

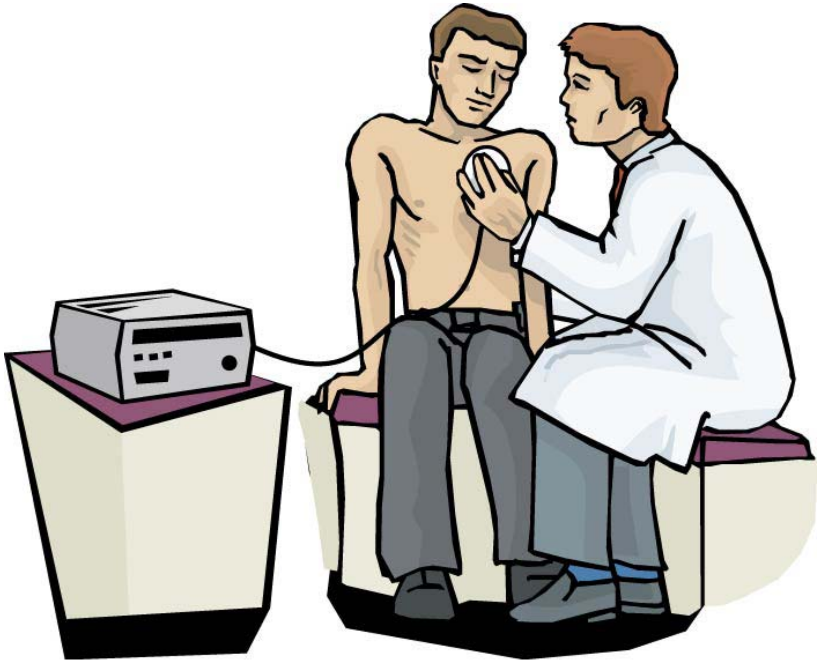
Today



Future with MICS

MICS Benefits – Doctor's Office

Today



Future with MICS

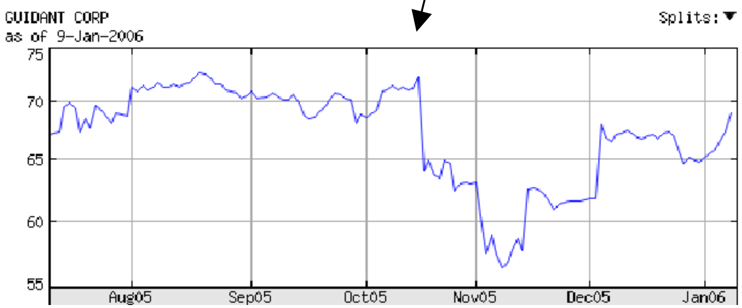
Potential Driver: Reliability Monitoring

- **Medical device failures exceptionally costly**
  - **Example 1: Recent Guidant battery issues**

    Recall and 15% sales drop
  - **Example 2: St Jude cosmic radiation memory problem**

    60 reported failures out of 36000 devices

    Remote monitoring could substantially reduce patient impact and cost



Extract from Physician Letter:
Oct-6th-2005, St Jude
http://www.sjm.com/companyinformation/physicianletter.html

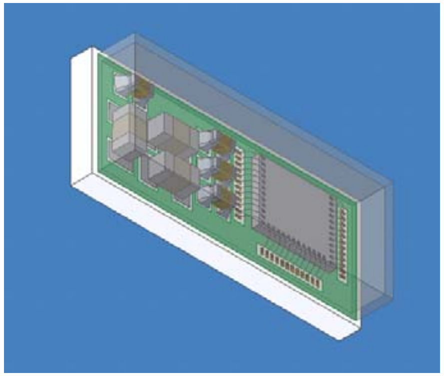
It is important to note that the opportunity for early detection will increase with more frequent follow-up intervals. As shown in the table below, increasing monitoring frequency would reduce relative patient risk.

Follow-up Frequency	Probability of Occurrence*
6 months	0.0000163
3 months	0.0000082
1 month	0.0000027

* Predicted risk of patient requiring VT/VF therapy and not receiving therapy due to this anomaly during the indicated follow-up period. The analysis assumes

Challenges

- **Low Power Consumption**
  - Low TX/RX current <6mA, battery considerations
  - Low sleep/listen current, ideally <100s of nA
- **Minimum External Components**
  - RF module <3x5x10 mm
  - Fewer components => higher reliability, lower cost, smaller size
- **Reasonable data rates**
  - Pacemaker applications >20 kbps and higher projected in the future
- **Operating range**
  - Require ~2 m to improve on existing links (short range inductive)
  - Antenna matching, fading and body loss typically 40-45 dB
- **Reliability**
  - Data and link integrity, selectivity and interference rejection



Module size 3 x 5 x 10 mm

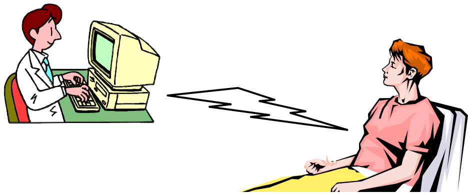
Design Solutions

- **Key Concept – Duty Cycle**
  - Duty cycle normal data exchange for given data rate
  - Duty cycle sniffing for wake-up
  - Turn off sub-systems in chip when not required
- **Use the highest possible data rate for required sensitivity**
  - Apply concept even for systems that require low data rates (low kHz range)
  - Sending data in short bursts conserves power
  - Reduces time window for interference and easier supply decoupling
- **High Data Integrity**
  - Reed-Solomon Forward Error Correction, CRC error detection
  - Capable of several years continuous operation without error
- **High Level of Integration**
  - Sub-micron CMOS RF technology

ULP Implantable Transceiver (ZL70101)

MICS and ISM Band Transceiver:

- Negligible standby current
- high data and low error rates in a small footprint



Technology:	0.18 um RF CMOS
Supply Voltage:	2.1 - 3.5 V Battery
Radio Frequency:	402-405 MHz (MICS-Band)
Type of RF link	Bi-directional, half duplex
Modulation Scheme:	FSK
Raw Bit Rate:	800 / 400 / 200 kbits/s
Operating Current:	5mA TX/RX down to <1mA
Sleep Current:	< 250 nA
Ext. comps:	3 (excluding antenna matching)
BER:	$<1.5 \times 10^{-10}$
Range:	~2 m

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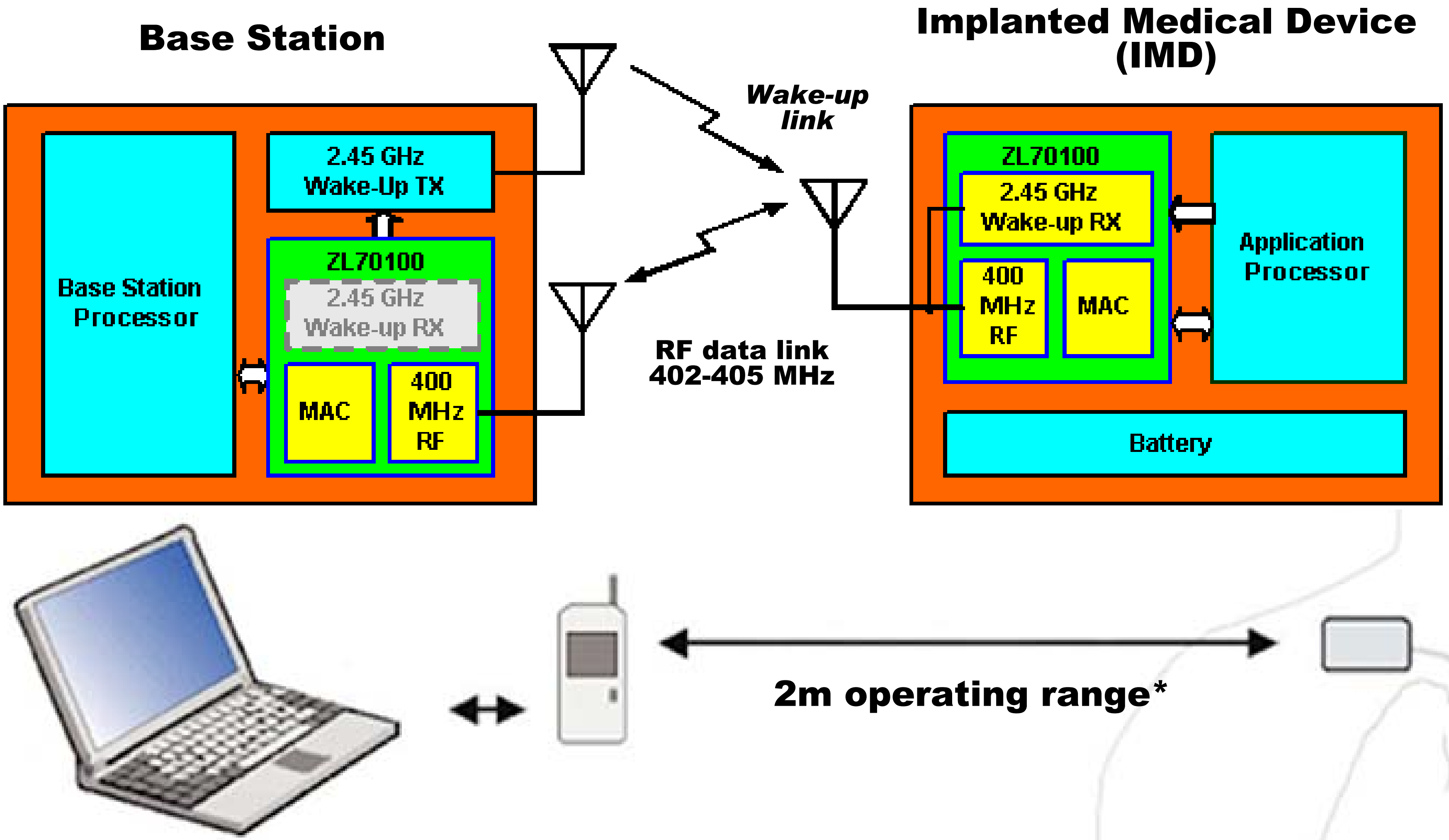
ZL70101 Key Features

- 12 Channels
  - 402-405 MHz (10 MICS)
  - 433-434 MHz (2 ISM)
- Selectable Data Rate
  - 200/400/800 kbps raw data rate
- High Performance Media Access Controller (MAC)
  - Auto error handling and flow control, Reed-Solomon, CRC
  - Typically <1.5 x10^{-10} BER
- Min. External Components
  - 3 pieces plus antenna matching
- Extremely Low Power
  - 5 mA continuous TX/RX
  - <1mA low power TX/RX
- Ultra Low-Power Wake-up Circuit
  - <250 nA
- Multiple Start-up Methods
  - 2.45 GHz signal
  - Pin Control

    (for Emergency messages, 400 MHz sniffing, low frequency inductive link sniffing or other wake-up methods)
- Standards Compatible
  - MICS, FCC, IEC

ZL70101 MICS System



* Dependent on antenna performance

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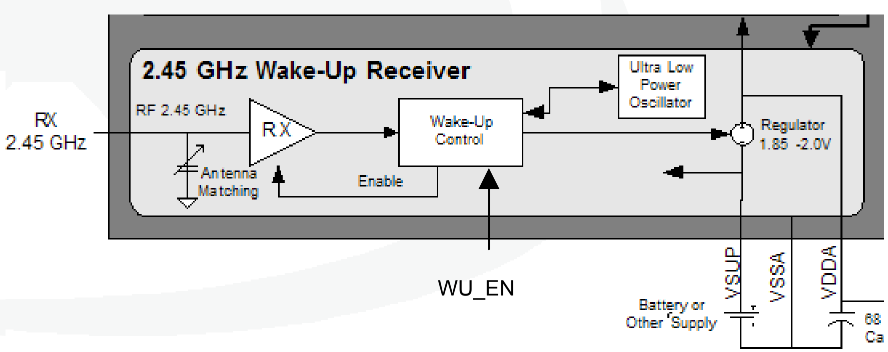
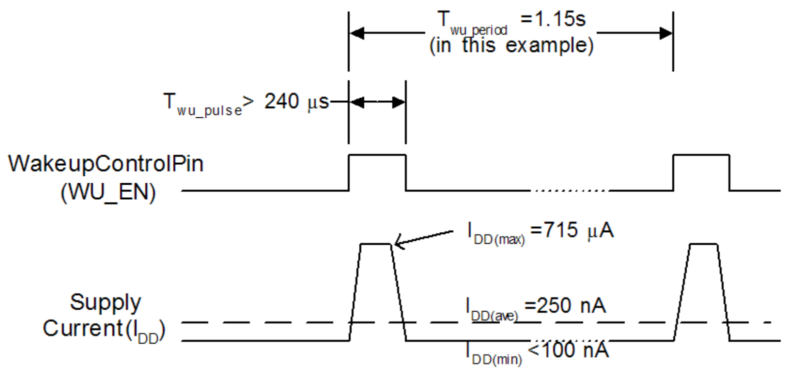
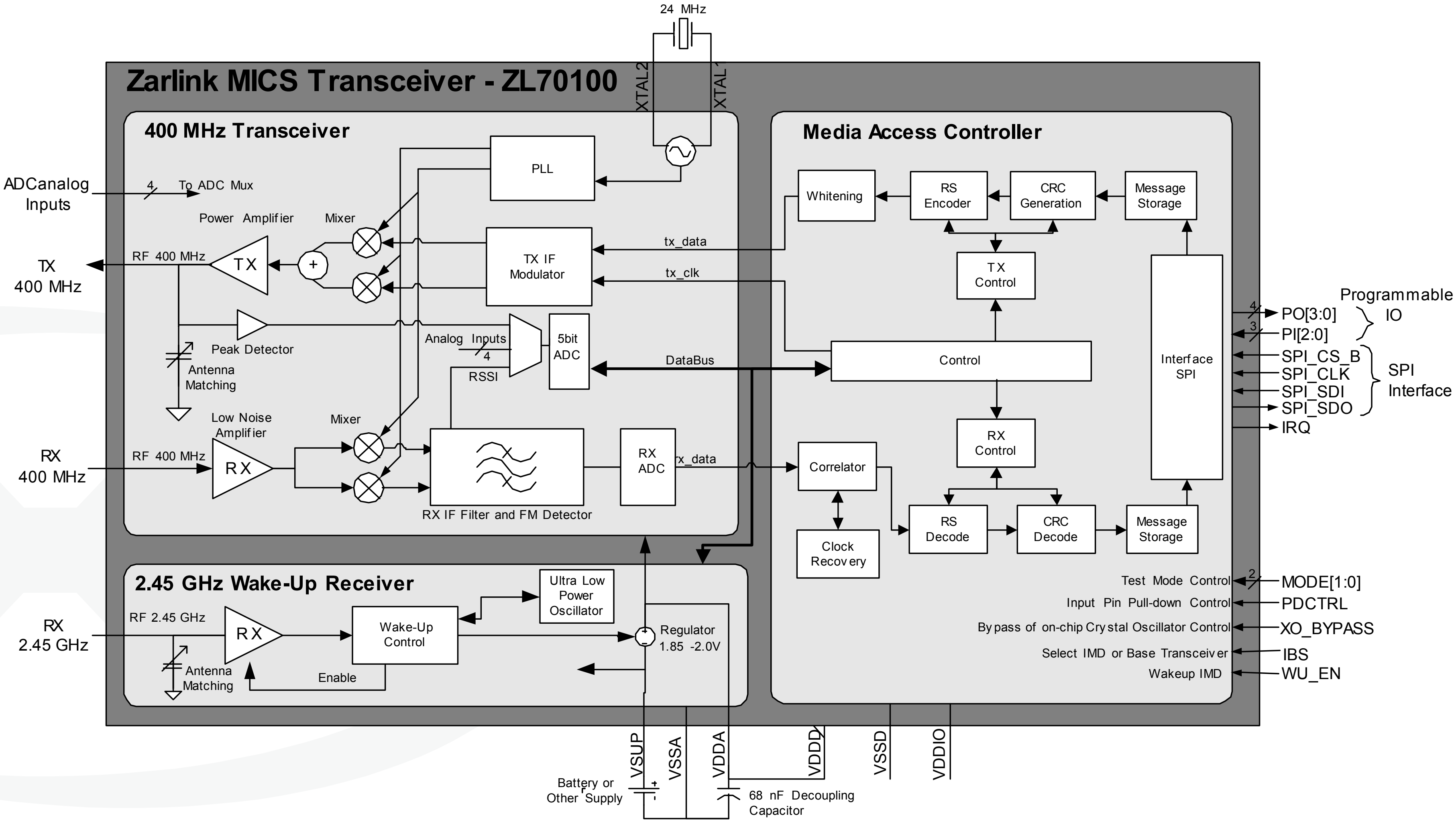
Wake-Up Receiver

- **Problem: MICS band limited to 25 uW (-16 dBm)**
- **Solution: Use band with more power 2.45 GHz (up to 20 dBm) and design synthesizer-less receiver**
  - **High Gain LNA and OOK detector**
  - **Manchester coding of pulses**
  - **250 nA average current for 1.15 second latency**
- **Possible to use for other sniffing/wake-up applications**



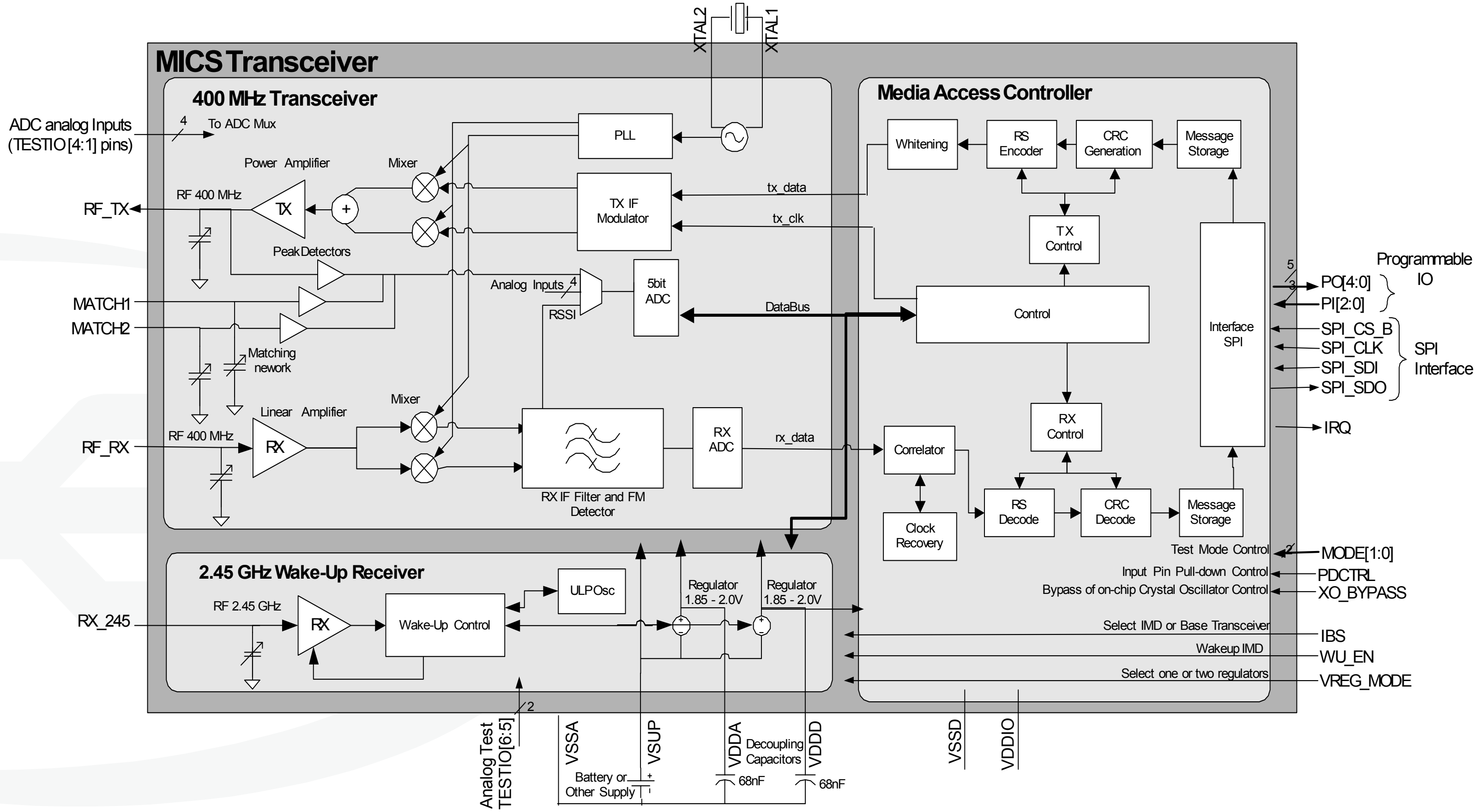


ZL70100 Block Diagram

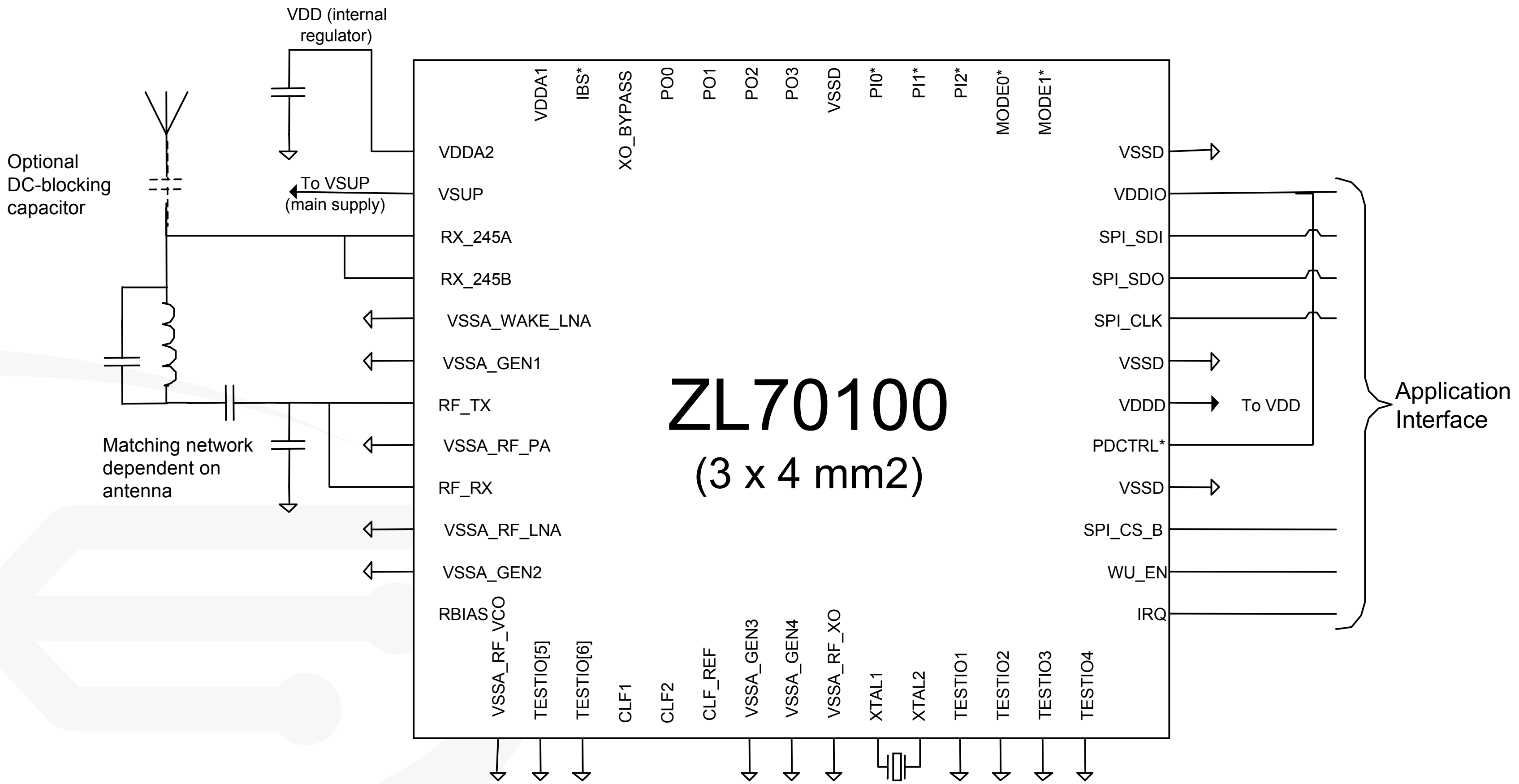


ZL70101 Block Diagram

- Improvement on ZL70100 (matching and power regulation)



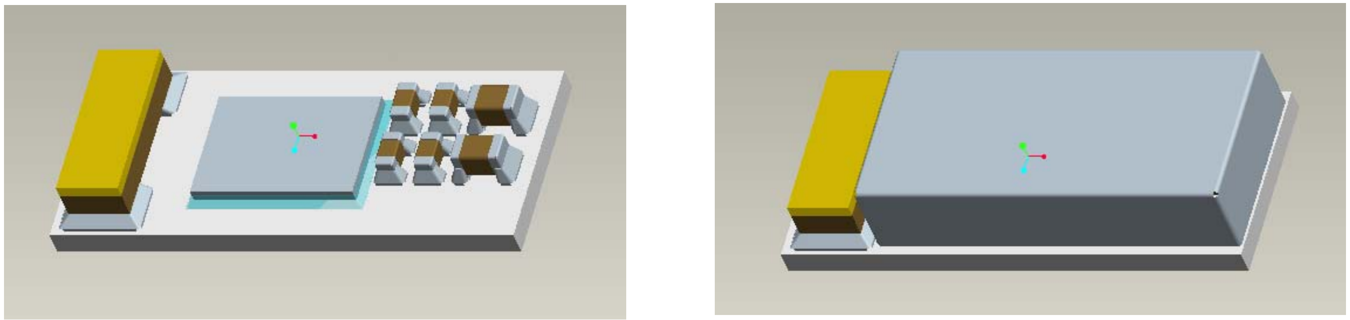
ZL70100 Example Implant Design



Note 1: *Inputs connected via internal pull-down to ground. Right-hand side pins do not need to be bonded out

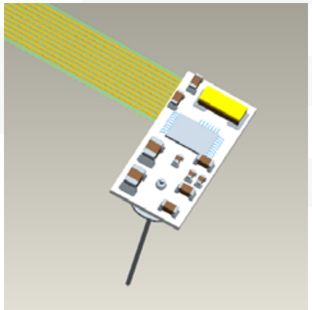
Note 2: Two supply voltages are required VSUP (the main supply,2.1-3.6V) and VDDIO (the digital IO voltage which may be 1.5V to VSUP)
VDD is an on-chip derived regulated supply which requires a 68 nF decoupling capacitor and connection of VDDA to VDDD

RF Module Technology for Implants

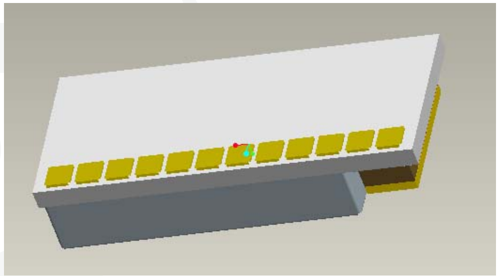


Ceramic, FR4, Rigid Flex

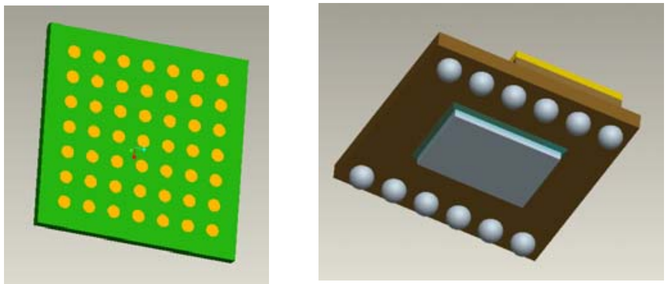
- I/O Connectivity



Flex



WireBond / Solder



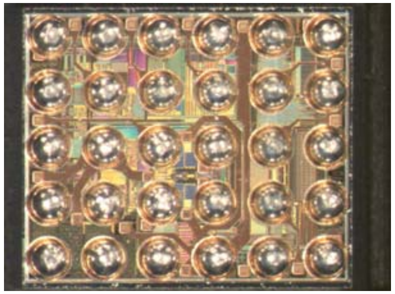
LGA / BGA

ULP Medical Transmitter (ZL70081)

Very high data rate transmitter

- low power
- small footprint
- designed for imaging applications

Technology:	0.35µm CMOS
Supply Voltage	2.6 - 3.2 V Battery
Radio Frequency:	400 - 440 MHz
Type of RF link:	Transmit only
Bit Rate:	2700 kbits/s
Operating Power:	5.2 mW
Ext. comps:	10



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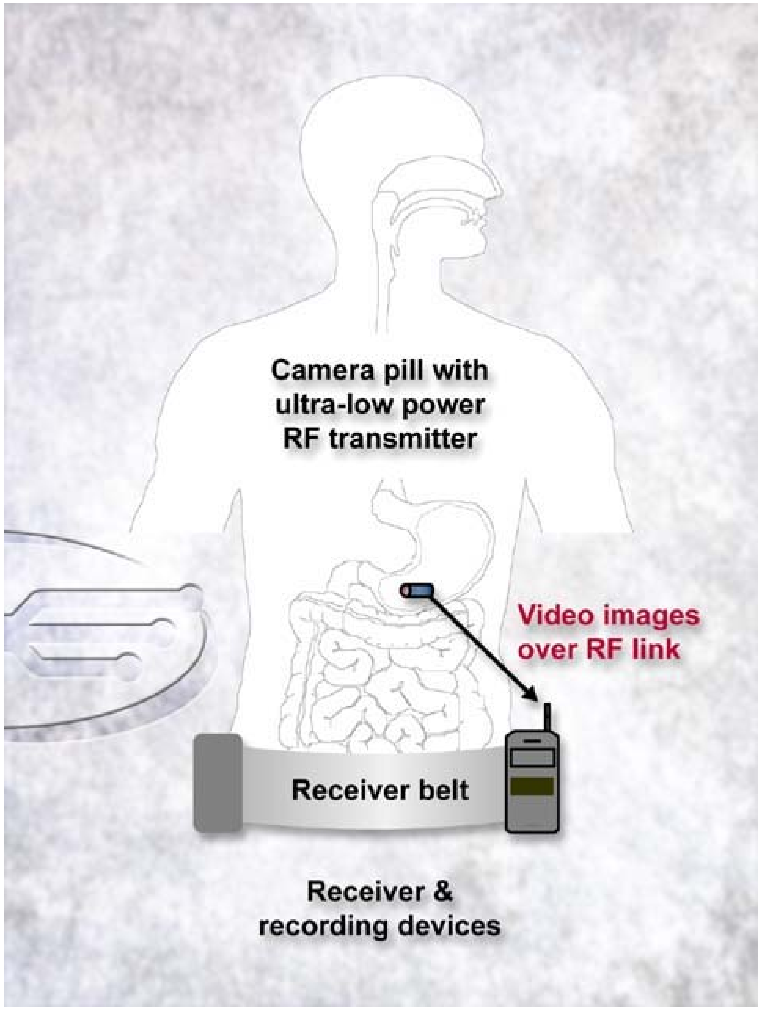
The Diagnostic Procedure
(Company: Given Imaging)

Healthy Small Bowel

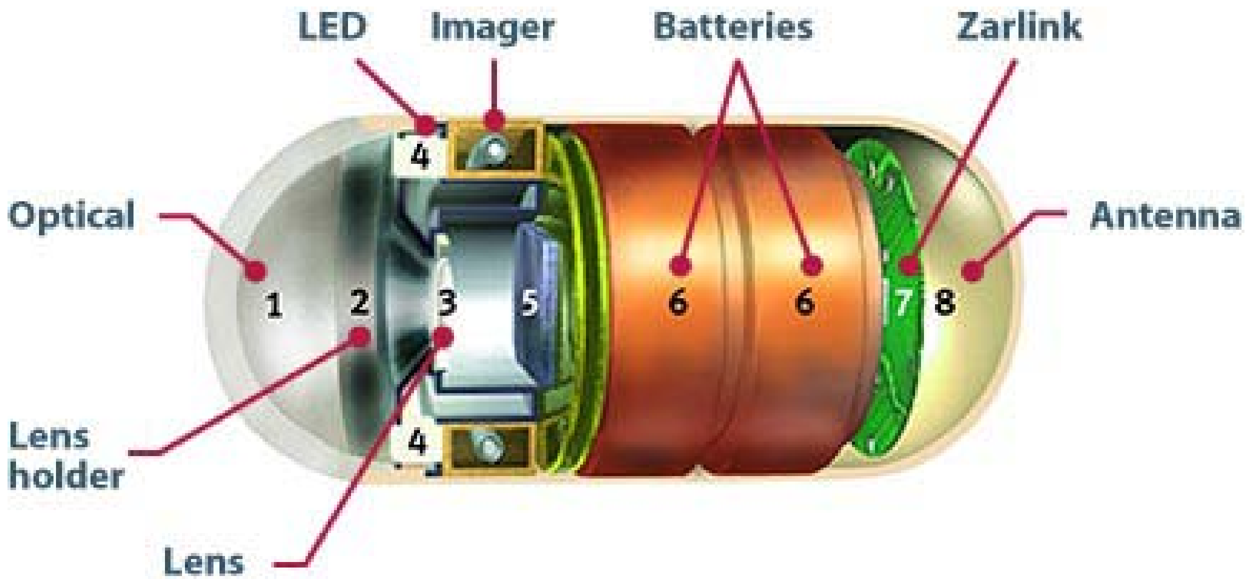


The Camera Pill (1)

Size: 11 x 26 mm Weight: < 4 gram View: 140 deg
Approximately 57,000 pictures during 8 hours

The Camera Pill (2)

- World's only Swallowable Camera Capsule, from Given Imaging, including Zarlink's ULP RF Transmitter



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ULP Audio Transceiver (ZL70262)

Hearing Aid wireless link:

- Device programming
- Ear to ear volume control
- Ear to ear communication for active noise cancellation and directional hearing

Technology:	0.18 μm RF CMOS
Radio Frequency:	915 MHz (Americas) / 863-865 MHz (Europe)
Type of RF link:	Bi-directional, half duplex
Bit Rate:	186 kbits/s
Current Consumption:	<2 mA from 1.05 - 1.5 V Battery (cf ~90 mA Bluetooth)
Range:	4 meters
Externals:	2 (Xtal,Res)

Summary

- RF integrated circuits for the MICS and ISM bands will open up a new range of clinical applications for next-generation medical devices.
- The development of such circuits requires leading-edge technology and design with specific attention to power consumption
- Integrated circuits, modules are available now and are being used in the latest medical devices development

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Opportunities for Research and Development

- Further characterization of RF propagation in and around the body is required, fading effects, interferer analysis in various countries
- Electrically small antennas for the body environment
- Ultra Low-Power architectures
- Ultra Low-Power coding schemes
- Development of MEDS band
  - MEdical Data Service
  - Regulatory approval and definition still in progress
  - 401-402 and 405-406 MHz, 100 kHz channels
  - For external medical applications (eg blood oximeters, ECG)
- Currently servicing existing applications but…
  miniaturized radios and associated power systems can open up new applications

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