WHITE PAPER

Ultra Low-Power RF Communications for Implanted Medical Applications and Low Duty-Cycle Systems

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The development of integrated circuits (ICs) and medical devices and has evolved in concert over the last 30 years. Circuit technology has facilitated the evolution of increasingly complex, highly integrated and smaller medical devices. At the same time, burgeoning healthcare costs combined with a more affluent, more obese and longer living population has created demand for new applications and therapies relying on implanted medical devices that are wirelessly linked to base stations. Implanted medical devices include stimulatory devices such as pacemakers, implantable cardioverter defibrillators, neurostimulators and cochlea implants and measurement or control devices such as drug infusion, implanted diagnostic sensors and the very rapidly growing implanted diabetes monitor.

Key to these new implanted devices and therapies is ultra low-power radio frequency (RF) IC technology. This article will briefly introduce the evolution of wirelessly enabled implanted medical devices, and take a more detailed look at the performance factors and challenges considered in the design of an ultra low-power RF communication IC intended specifically for medical applications in the 402-405 MHz band or 433 MHz ISM band.

The ZL70100 MICS transceiver offers exceptionally low power consumption while providing a high data rate. The transmit and receive current is less than 5 mA when operating at a data rate of up to 800 kbps. The circuit features a unique ultra low-power wakeup system operating at 2.45 GHz that enables an average sleep/sniffing current of less than 250 nA. System integration is high and only three external components (crystal and two decoupling capacitors) and a matching network are required.

Low Power Performance – Duty-Cycling and “Sniffing”

Despite the performance afforded by modern IC technology, electronic systems associated with implanted medical applications present formidable low-power design challenges. For example, most implanted pacemakers have lifetime requirements of greater than seven years with maximum current drains in the order of 10-20 uA. The communication systems are budgeted at total currents averaged over the device lifetime of no more than about 15% of the total power budget or 2-3 uA due to the current consumption demands of supporting pacing therapy.

Receivers in implanted medical systems must periodically “sniff” or monitor for an external communication device, and conserve power by remaining off in a very low power state when not sniffing. To save power, the time between sniffs should be as long as possible, but this is typically limited to 1-10 seconds due to application considerations such as the need for delivering therapy.

Generally, the principles of duty-cycling and receiver sniffing are basic concepts that are applicable to many low-power systems. This is becoming increasingly important with the very rapid growth of short-range wireless sensors, deployed in applications such as hostile or difficult industrial environments and security and tracking systems, where battery power consumption is important. Existing protocols such as Zigbee, Bluetooth and 802.11 do not have very low power sniffing mechanisms that support these low duty-cycle applications.

Brief History of Implanted Medical Communication

Traditionally, communication systems in implanted medical devices have used very short-range magnetic coupling. These near-field systems require close coupling between the programmer and medical device and often have data rates of less than 50 kbps.

To overcome range limitations, in the mid-1990s Medtronic, the world's largest implanted medical device manufacturer, petitioned the U.S. Federal Communications Commission (FCC) for spectrum dedicated to medical implant communication. The 402-405 MHz Medical Implant Communication Service (MICS) band was recommended for allocation by ITU-R Recommendation SA1346 in 1998. The FCC established the band in 1999 with similar standards following in Europe [1,2]. The allocation of this band supports the use of longer range (typically two meters), relatively high-speed wireless links.

The MICS band overcomes the limitations of dated inductive systems and facilitates the development of next-generation implanted medical devices delivering improved patient care. This is especially important as escalating health costs drive adoption of home-based patient monitoring. Some of the benefits of this new technology are illustrated in Figure 1.

The 402-405 MHz band is well suited for this service, due to the signal propagation characteristics in the human body, compatibility with the incumbent users of the band (meteorological aids such as weather balloons), and its international availability. Note that higher frequencies suffer from greater body attenuation, although this is somewhat compensated for by improved antenna gain. To enable the use of the MICS band, implanted medical devices require an ultra low-power, high-performance transceiver discussed later in this article.

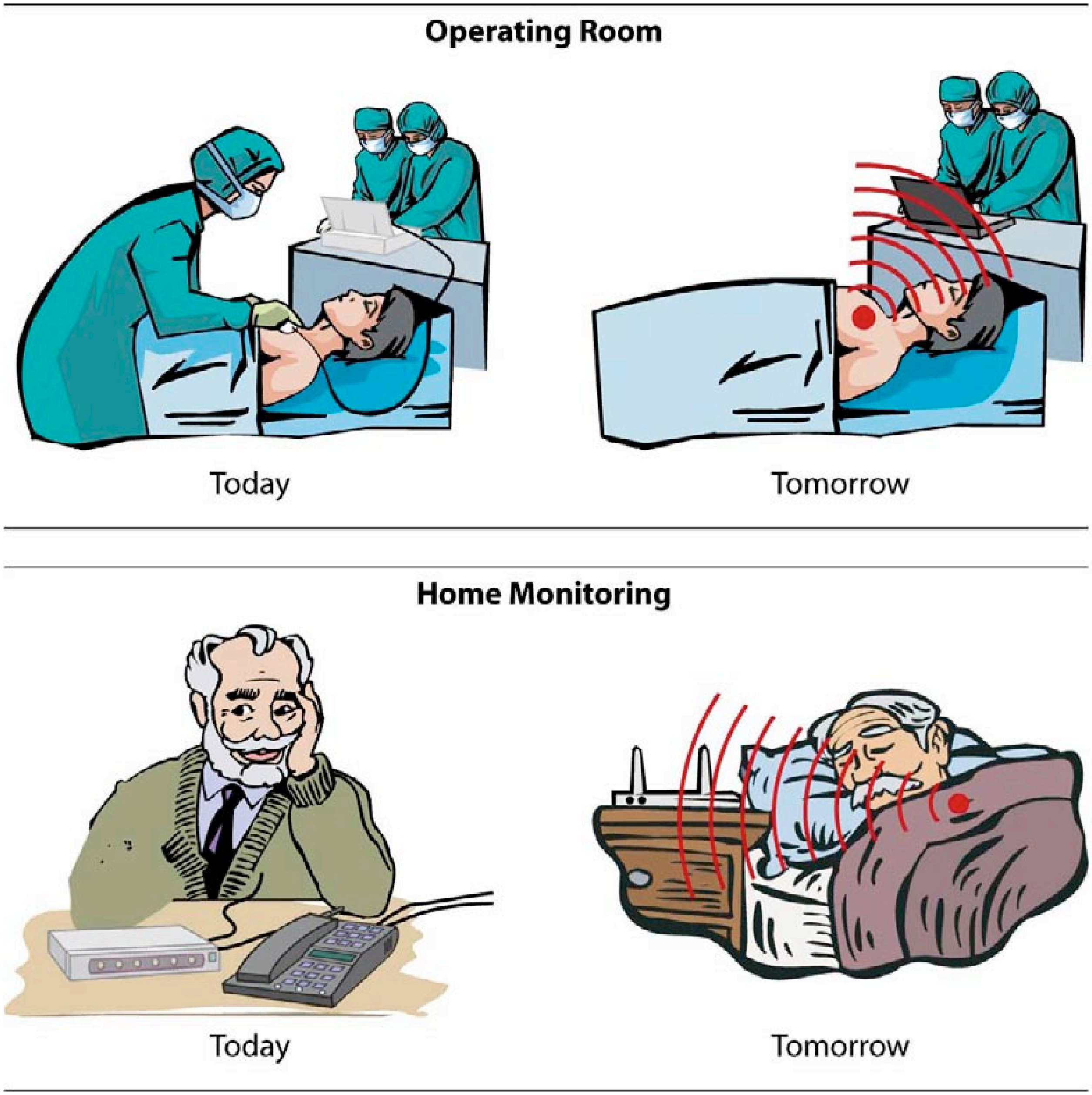


Figure 1. Example benefits of MICS band technology

Medical Implant Transceiver Design Considerations

The design of transceivers for implanted medical devices is challenged by the following basic requirements:

- Low power during 400 MHz communication is required. Implant battery power is limited and the impedance of implant batteries is relatively high. This limits peak currents that may be drained from the supply. During communication sessions, current should be limited to less than 6 mA for most implantable devices;
- Low power when asleep and periodically “sniffing” or looking for a wakeup signal is required.

- Minimum external component count and minimum physical size are important factors. An RF module for a pacemaker should not be more than ~3x5x10 mm3 in order to fit within typical pacemaker cans. Furthermore, implant-grade components are expensive and high levels of integration may reduce costs. Integration has the additional benefit of increasing overall system reliability;
- Reasonable data rates are demanded. Pacemaker applications are currently demanding >20 kbps with higher data rates projected for the future;
- High system and data transmission reliability;
- Selectivity and interferer rejection especially from TETRA radios in Europe;
- Typically greater than two-meter range since the MICS band is designed to improve upon the very short-range inductive link. Longer ranges imply good sensitivity is needed since small antennas and body loss affect link budget and allowable range. Antenna, matching, fading and body losses are quite variable with losses as high as 40-45 dB.

The transceiver presented in this article addresses all of these requirements. Some specific tradeoffs and the device performance are discussed below.

Medical devices may be categorized into those that use an internal non-rechargeable battery (e.g. pacemakers) and those that couple power inductively (e.g. cochlea implants). The former heavily duty-cycle the operation of systems to conserve power. The transceiver is off most of the time, therefore the off-state current and the current required to periodically look for a communicating device must be extremely low (<1-2 uA). In both cases, low power (<6 mA) for transmit and receive is also required.

The transceiver presented has a peak RX/TX current consumption of <5 mA operating from a supply voltage of between 2.1-3.5 V. This current not only includes the basic RF transceiver current but also the media access controller (MAC) current. The MAC ensures the user receives high integrity data and automatically performs much of the required link maintenance. Furthermore, the MAC protocol offers a power-save timer that turns off the receiver in the implant for a programmable time after transmitting a packet. This helps conserve power if the implant momentarily has no information to send.

For minimum overall power consumption, defined in terms of Joules/bit, it is recommended that implantable transceivers should use the highest possible data rate that satisfies the application receiver sensitivity requirements. Systems that require low data rates (even in the low kHz range) should buffer data, operate at the highest data rate possible and exploit duty-cycling of the power states to reduce the average current consumption. Sending data in short bursts conserves power and reduces the time window allowed for interference. In addition, in systems with high battery impedance the power supply decoupling requirements may be more forgiving due to shorter bursts of charge drawn from capacitors.

The transceiver allows the user to select from a wide range of data rates (200-400-800 kbps) with varying receiver sensitivity. To facilitate this flexibility, the system uses either 2FSK or 4FSK modulation with 200 or 400 kSymbols/s and varying frequency deviations. The table below summarizes the allowable modulation modes, respective data rates and corresponding receiver sensitivity. Lower data rates and correspondingly higher receiver sensitivity may be attained by off-chip digital filtering. The transceiver has a MAC bypass mode of operation in which the radio is fully accessible. In this configuration, the user may develop customized protocols and data rates.

Modulation Mode	Data Rate (kbps)	Rx Sensitivity (µV)
4FSK	800	<90
2FSK - high rate	400	<35
2FSK - high deviation	200	<20

Note: The effective impedance at the Rx input is high (~1600 ohms)

Table 1. Data Rate versus Receiver Sensitivity

Overall System Architecture

An overall system architecture example is shown below in Figure 2. The Zarlink ZL70100 operates in both the implanted device and external base station. The base station includes additional circuitry to transmit a 2.45 GHz wakeup signal. The rationale behind using this wakeup method is discussed later. Once the system is started via the 2.45 GHz wakeup signal, data is exchanged using the 402-405 MHz MICS band transceiver.

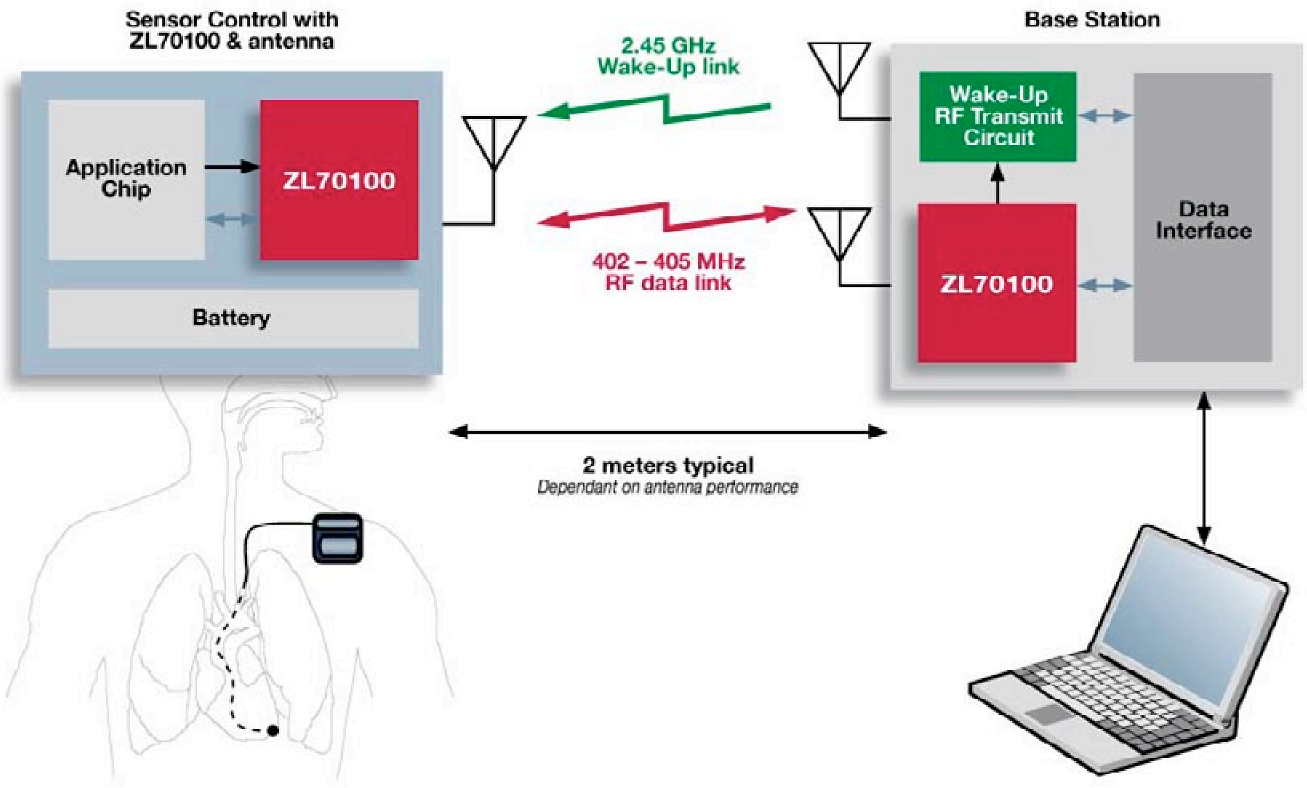


Figure 2. Overall system architecture, with the ZL70100 MICS transceiver operating in both the implanted medical device and base station.

The ZL70100 MICS chip, as shown in Figure 3, consists of three main sub-systems; a 400 MHz transceiver, a 2.45 GHz wakeup receiver and a MAC. The purpose and basic architecture of each of these sub-systems will be described in subsequent sections. The chip may be used as the transceiver in either an implanted medical device or a base station programmer as determined by the state of an input pin.

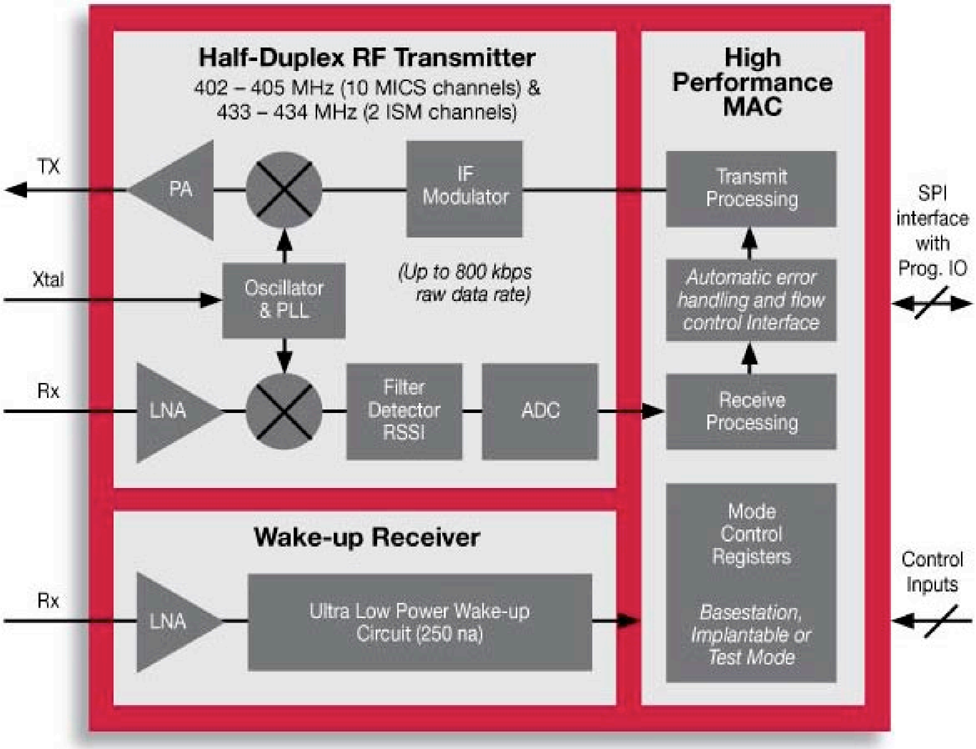


Figure 3. Block diagram of ZL70100 MICS transceiver showing the three main sub-systems; a 400 MHz transceiver, a 2.45 GHz wakeup receiver and a MAC

400 MHz Transceiver and MAC

The transceiver uses a low intermediate frequency (IF) super-heterodyne architecture with image reject mixers. The low-IF minimizes filter and modulator power consumption without the flicker noise and DC offset problems associated with high data rate, zero-IF architectures. An FSK modulation scheme reduces TX amplifier linearity requirements, thereby reducing power consumption and allowing for a simpler limiting receiver.

The 400 MHz transmitter subsystem, labeled half-duplex RF transmitter in Figure 3, consists of an IF modulator, mixer and power amplifier. The IF modulator converts a one- (2FSK) or two-bit (4FSK) asynchronous digital input data stream to an intermediate frequency. An up-converting mixer transforms the IF to RF frequency. Note that the local oscillator frequency is the same for both transmit and receive mode, which minimizes dead time between receiving and transmitting packets.

The output power of the TX power amplifier is register programmable in <3 dB steps from -4.5 dBm to -17 dBm (into a 500 ohm load). Internal antenna matching capacitor banks on all RF inputs allow for fine-tuning the matching network for maximum delivered output power for a given power setting and optimum receiver noise figure. The antenna tuning is an automatic calibration that uses a peak-detector coupled to an ADC along with a state-machine for calibration control.

The 400 MHz receiver subsystem amplifies the MICS band signal and down-converts from the carrier frequency to the IF. The LNA gain is programmable from 9 to 35 dB. Higher gain settings are recommended for implanted medical device transceivers while the lower gain settings may be applicable to base station transceivers that choose to use an external LNA. Programmability of LNA and mixer bias currents provides further flexibility in optimizing for desired linearity (IIP3), power consumption and noise figure.

A poly-phase IF filter is used to suppress interference at the image frequency and adjacent channels and limit the noise bandwidth. Limiters and a received signal strength indicator (RSSI) block follow the poly-phase filter. The RSSI measurement is converted by a 5-bit ADC and may be read by the industry-standard SPI interface. This is useful for performing the MICS clear-channel assessment procedure. Note that an external instrument must first determine a suitable useable channel via a process of clear-channel assessment defined in the MICS standards.

A specific protocol customized for high reliability medical applications has been developed. This protocol is handled by the MAC and includes the following main features:

- Correction and detection of errors, using Reed-Solomon forward error correction (FEC) and cyclic redundancy code (CRC) error detection. The effective BER after FEC and CRC is better than 1.5 × 10-10 given a raw radio BER of 10-3;
- Automatic retransmission of data blocks in error and flow control to prevent buffer overflow;
- Capable of sending MICS emergency command and high priority messages;
- Handling of link watchdog to ensure link is shutdown after five seconds without successful communication;
- Provision of link quality diagnostics and control of automatic calibrations.

The rich feature set of the communication protocol relieves the user application of many link maintenance activities. The communication link is simply viewed as a receive and transmit buffer accessible via the SPI interface. Buffer conditions that require user attention are flagged by interrupts allowing the user to optimally maintain data flow.

Ultra Low-Power Wakeup Receiver

Most implant applications will infrequently use the MICS RF link due to the overriding need to conserve battery power. In very low power applications, the transceiver will be asleep in a very low current state for the majority of the time. Except when sending an emergency command, systems that use the MICS band must first wait for the base station to initiate communications following a clear channel assessment procedure. Periodically, the implanted transceiver should listen for a base station that wants to begin communication. This “sniffing” operation should be frequent enough to provide reasonable startup latency, consume a very low current since it will occur regularly, and be immune to noise sources that invoke an erroneous startup.

For a very low power receiver, an OOK modulation scheme is recommended since it removes the need for a local oscillator and synthesizer in the receiver. Further simplification, and hence power saving, is gained by using a frequency band for the startup process which is of reasonable power. The 2.45 GHz short-range device (SRD) band satisfies such a requirement and at 100 mW EIRP (in USA, 10 mW in a few countries such as Japan) is up to 36 dB higher in power than the 25 uW maximum allowed in the MICS band.

The wakeup system uses an ultra low-power RF receiver, operating in the 2.45 GHz SRD-band, to read OOK transmitted data. The main function is to detect and decode a specific data packet that is transmitted from a base station and then switch on the supply to the rest of the chip. The data packet contains transceiver setup information. The chip may also be started directly by pin control as would be needed for either a base station starting up, an implant sending an emergency command or an implant using an alternative wakeup system. For example, one such alternative wakeup system is to use the available RSSI measurement facility to sense a Base 400 MHz communication.

To reduce the average current consumption of the wakeup subsystem, the wakeup system is strobed by either an application-generated strobe pulse applied to a pin or an internally generated strobe pulse created using a low power (<400 nA) internal 25kHz oscillator. During a strobe the receiver is turned on and sniffs for a valid wakeup signal. The user selects an interval between sniffs (Twu_period) dictated by the application's required wakeup latency and the average current consumption, which for external strobing is given by IDD(average) = 100 nA + 715×240×10-12/Twu_period where the 2.45 GHz RX consumes a maximum of 715 µA when sniffing.

In the example calculation (Figure 4) 250 nA (external strobe) or 650 nA (internal strobe) is achieved including 100 nA budgeted for leakage current. The calculation in this example assumes a time between strobes of 1.15 s. Actual measured leakage current at room temperature is less than 10 nA, meaning the 100 nA budget is a very conservative design buffer.

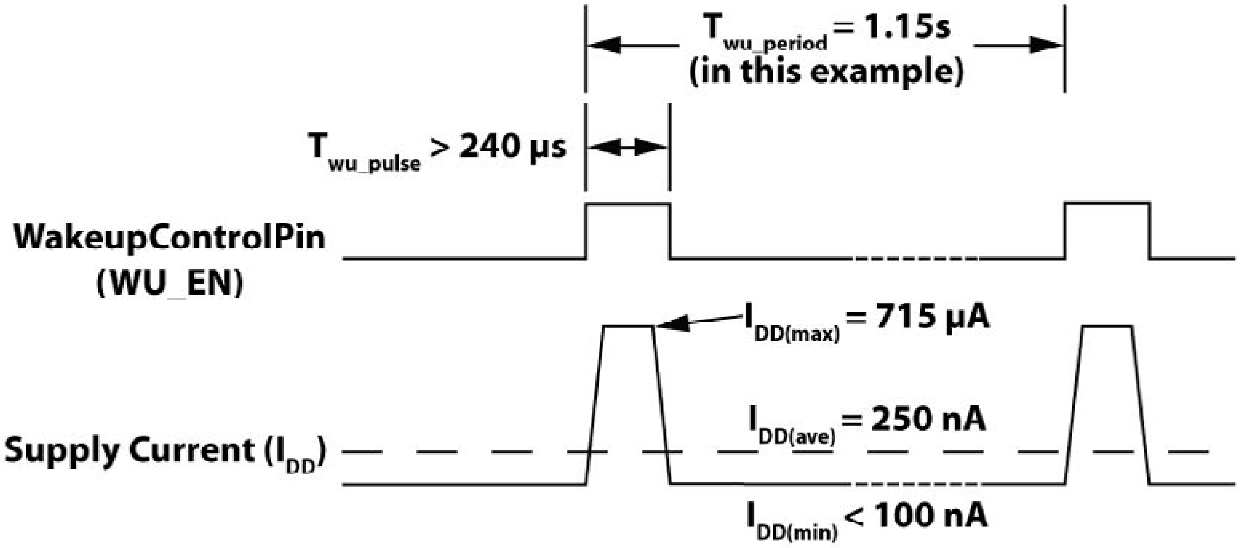


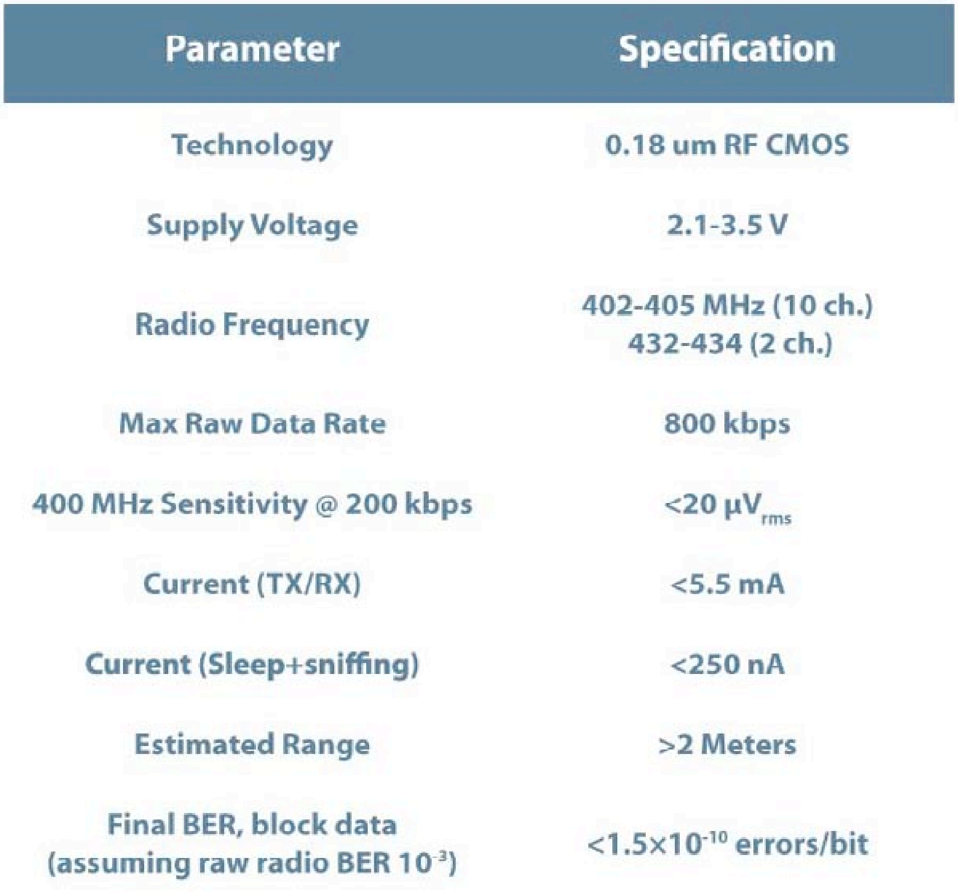
Figure 4. Example current consumption of low power wakeup system

The low power wakeup method presented may be used as a standalone wakeup system for other communication applications. Consider, for example, an 802.11 WLAN battery operated system requiring very long battery life in an application where battery replacement is difficult or costly. The 2.45 GHz wakeup system could be used to minimize sleep/sniffing current and only operate the much higher power 802.11 protocol when a communication session is desired.

Conclusion

An ultra low-power high performance RF transceiver for implanted medical applications has been presented. The ZL70100 MICS transceiver is highly integrated and includes a complete MAC that provides the user application with a high effective BER. The key RF performance parameters are summarized below. Of special interest is the very low power 2.45 GHz sniffing circuit that may be applied to a variety of low duty-cycle power constrained applications.

Given these performance capabilities the communication systems of future generation medical devices will be significantly enhanced.



Parameter	Specification
Technology	0.18 um RF CMOS
Supply Voltage	2.1-3.5 V
Radio Frequency	402-405 MHz (10 ch.) 432-434 (2 ch.)
Max Raw Data Rate	800 kbps
400 MHz Sensitivity @ 200 kbps	$<20\ \mu V_{rms}$
Current (TX/RX)	<5.5 mA
Current (Sleep+sniffing)	<250 nA
Estimated Range	>2 Meters
Final BER, block data (assuming raw radio BER 10^{-3})	$<1.5\times10^{-10}$ errors/bit

Table 2. Measured Performance Summary

References

1) FCC Rules and Regulations 47 CFR Part 95, Subparts E (95.601-95.673) and I (95.1201-95.1219) Personal Radio Services, November 2002.

2) TSI EN 301-839, Parts 1 and 2 and ETSI EN 301-489 Part 27.

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