# St. Jude Medical: Enhanced MICS (eMICS)

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by

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## ABSTRACT

St. Jude Medical: Enhanced MICS (eMICS)

Devanshi Shah

Heart disease is one of the most prevalent diseases in the world. The survival chances for patients with ventricular fibrillation/ventricular tachycardia reduces significantly as time passes without treatment and even after getting timely treatment recurring episode are common. These patients can benefit from an Implantable Cardioverter Defibrillator (ICD) which can monitor heart rhythm and provide immediate treatment. Due to the ever changing physical conditions and disease progression, the ICD needs to collect diagnostic data as well as support programming by the physician. The ICD uses inductive telemetry and radio-frequency telemetry for the communication with the external devices such as a programmer or a monitor. Inductive telemetry uses less energy than RF telemetry but has a very short range of communication. In addition to inductive telemetry, the St. Jude Medical ICD supports 2.45 GHz band based asynchronized wakeup and 400 MHz MICS band based synchronized wakeup. The 2.45 GHz band based wakeup has limited wakeup range and the 400 MHz MICS based synchronized wakeup has limited availability for connection because it requires synchronization with the base station. The enhanced Medical Implant Communications Service (eMICS) algorithm is a firmware based algorithm which addresses the issues with other two wakeup schemes and provides fast, robust, and seamless wakeup. This thesis describes the design, implementation, and initial testing of eMICS algorithm on the Unity device platform in Technology Project Management (TPM) phase. The eMICS automated test tool developed at St. Jude Medical was used to test the eMICS algorithm under a controlled lab environment, typical home environment, typical hospital/clinic environment, and in the field. The project was successfully completed and transferred to Product Project Management (PPM) phase. However, the suggested duration of 60-90 seconds for sniff interval which will cause the least effect on the battery life was found unacceptable, and there is

also a strong need for energy efficient hardware which draws minimal amount of current during each sniff. Therefore, St. Jude Medical is collaborating with the hardware vender to implement eMICS algorithm in the next version of hardware.

Keywords: ICD, Inductive Telemetry, RF Telemetry, Wakeup scheme, MICS

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# 1. Background

Heart disease is one of the leading causes of death all over the world. Heart disease refers to different types of heart conditions; heart failure is one of such conditions. Heart failure is most commonly a result of myocardial infarction/heart attack. A heart attack occurs when blood flow to the heart is blocked due to obstruction in the blood vessels. The heart muscle cells die or become permanently damaged due to lack of oxygen rich blood [1].

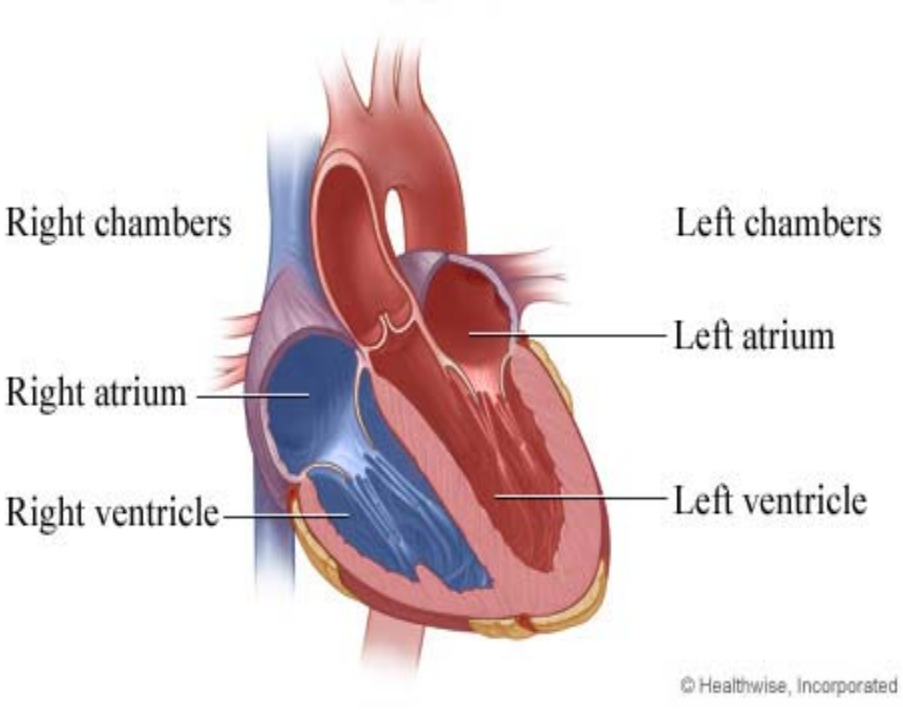


**Figure 1: Chambers of the heart [2]**

The heart has two atriums and two ventricles as shown in Figure 1. The right atrium receives oxygen-poor blood from the body and pumps it to the right ventricle, which then pumps it to the lungs. The left atrium receives oxygen-rich blood from the lungs and pumps it to the left ventricle, which then pumps it to the body [2]. This sequence of heart beats creates the rhythm pattern which is called heart rhythm.

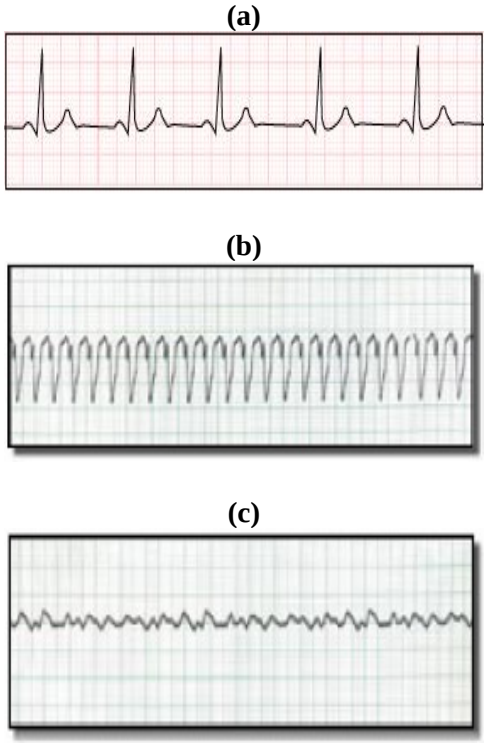


**Figure 2: Heart Rhythms:**

**(a) – Sinus Rhythm, (b) – Ventricular Tachycardia Rhythm, (c) – Ventricular Fibrillation Rhythm**

Figure 2(a) shows the normal heart rhythm called sinus rhythm, Figure 2(b) shows the ventricular tachycardia rhythm – a faster but regular rhythm starting in ventricles, and Figure 2(c) shows the ventricular fibrillation rhythm – a faster and irregular rhythm starting in ventricles. Some forms of ventricular tachycardia may get worse and lead to ventricular fibrillation. Both ventricular tachycardia and ventricular fibrillation are life threatening. Patients with heart failure suffer from ventricular tachycardia/ventricular fibrillation and are at risk of Sudden Cardiac Arrest (SCA) also known as Sudden Cardiac Death (SCD) where the heart suddenly stops working. SCD can be averted, if this abnormal heart rhythm is fixed right away by delivery of an electrical jolt also called defibrillation [1]. The patient's chance of survival reduces 7-10% every minute that passes without defibrillation. Even after getting timely treatment, the patient is at an increased risk of recurring episode [2]. Each year, about 795,000 people in the United States experience a new or recurrent heart attack. On average, every 40 seconds someone has a stroke

and these numbers are going up due to the prevalence of overweight individuals and an increase in the average life span for humans [4].

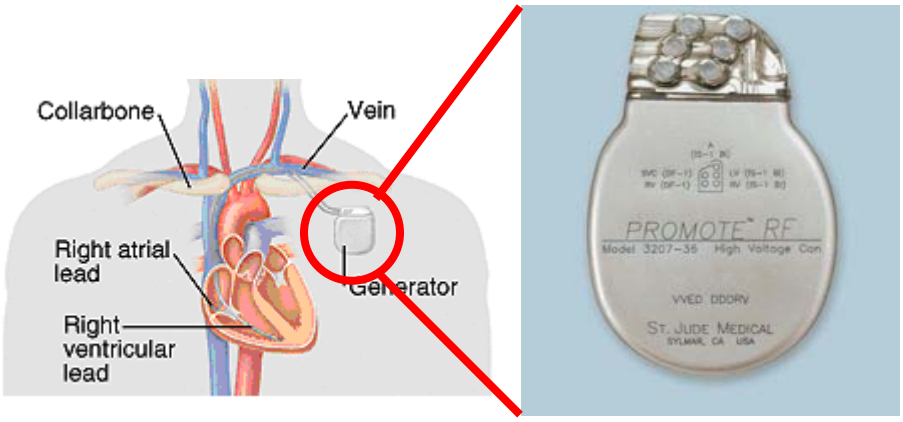


**Figure 3: Implanted ICD [5]**

Figure 3 shows an Implantable Cardioverter Defibrillator (ICD), which is a battery powered device, programmed to monitor heart activity, detect arrhythmia, and correct it by delivering an electrical jolt to convert life-threatening abnormal rhythm to sinus rhythm [5]. The ICD is typically implanted near the collarbone and has wires with electrodes on the ends attached to it. These wires, also called leads, are positioned in one or more heart chambers. These leads are used by the ICD to monitor the electrical signal from the heart as well as to deliver low power or high power electrical pulses to the heart. ICD use has been increasing by 20% to 30% per year in the United States. Several clinical trials have shown that the ICD can be effective for both primary prevention (for patients at increased risk of SCD but without documented ventricular tachycardia, ventricular fibrillation, or cardiac arrest) and secondary prevention (for patients resuscitated after unstable ventricular tachycardia or ventricular fibrillation or cardiac arrest) of SCD [6]. Myocardial infarction impairs the heart's ability to pump blood which results in insufficient cardiac output. Modern ICDs can help with this issue by performing biventricular pacing – delivery of low power electrical pulses in both the ventricles so that the chambers contract at the same time to increase cardiac output.

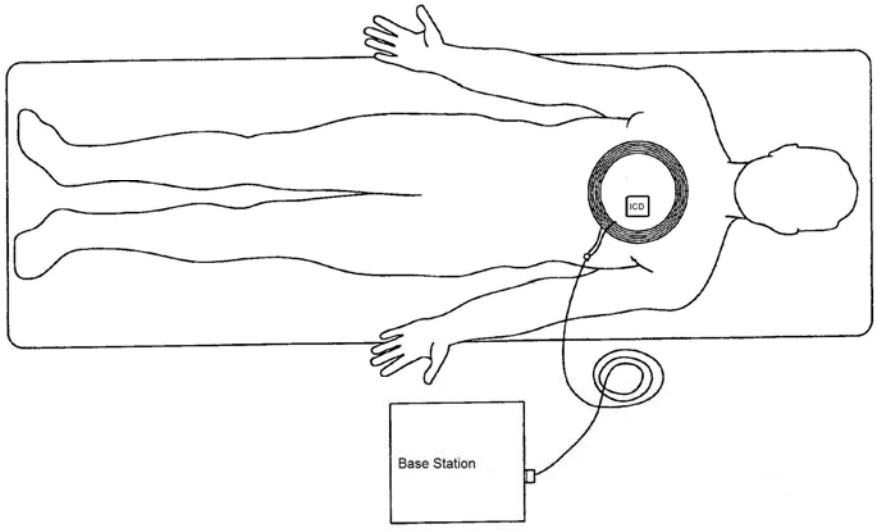


**Figure 4: Inductive Telemetry**

After the implant, there is a need to communicate to the ICD to retrieve stored diagnostic data from the ICD and to change programmable clinical parameters in the ICD. An external device called the base station is used to communicate to the ICD. Traditionally inductive telemetry has been used for communication between the ICD and the base station, as shown in Figure 4. This type of telemetry is based on inductive coupling between two closely-placed coils using the mutual inductance between these coils. It is also referred to as near-field telemetry because the coils must typically be closely situated. An ICD contains a coil along with a telemetry circuit sealed in a metal housing, and the telemetry wand contains another coil. Due to a limitation in communication range of only a few inches, the telemetry wand needs to be placed on the body surface over the ICD implant site. The inductive telemetry limits the patient's mobility as the telemetry wand needs to be connected to the base station which performs monitoring and programming.

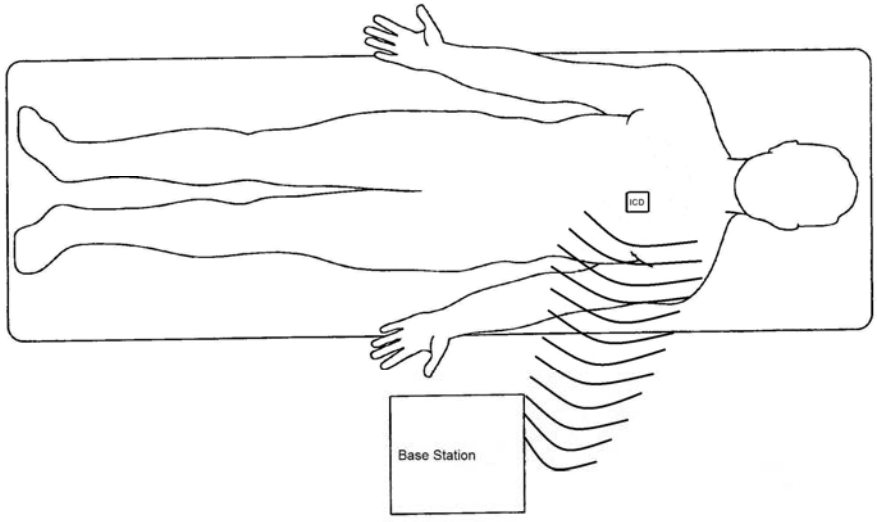


**Figure 5: RF Telemetry**

Modern ICDs use far-field radio-frequency (RF) telemetry as shown in Figure 5, which enables wireless communication between the ICD and the base station. The ICD and the base station both contain a RF transceiver and use radio-frequency for communication. The communication range for RF telemetry is a few feet, which is much longer than inductive telemetry. However, the ICD battery also needs to power the RF transceiver, so RF telemetry consumes much more energy than inductive telemetry.

Patients who have undergone implantation of an ICD require constant monitoring for a few days post surgery to make sure the ICD is functioning as expected, and there are no other post surgery complications. Long range RF telemetry is much more convenient for the bedside monitoring than inductive telemetry in hospitals as shown in Figure 6(a). Patients with an ICD also require periodic follow-ups to ensure safety and efficacy of the implanted device. International guidelines suggest that these patients should be followed at 3 - 6 months intervals depending on the patient's clinical status and device battery status [8]. An increasing number of patients and expanding indication for use of the ICD necessitates better and faster ways for follow-up.

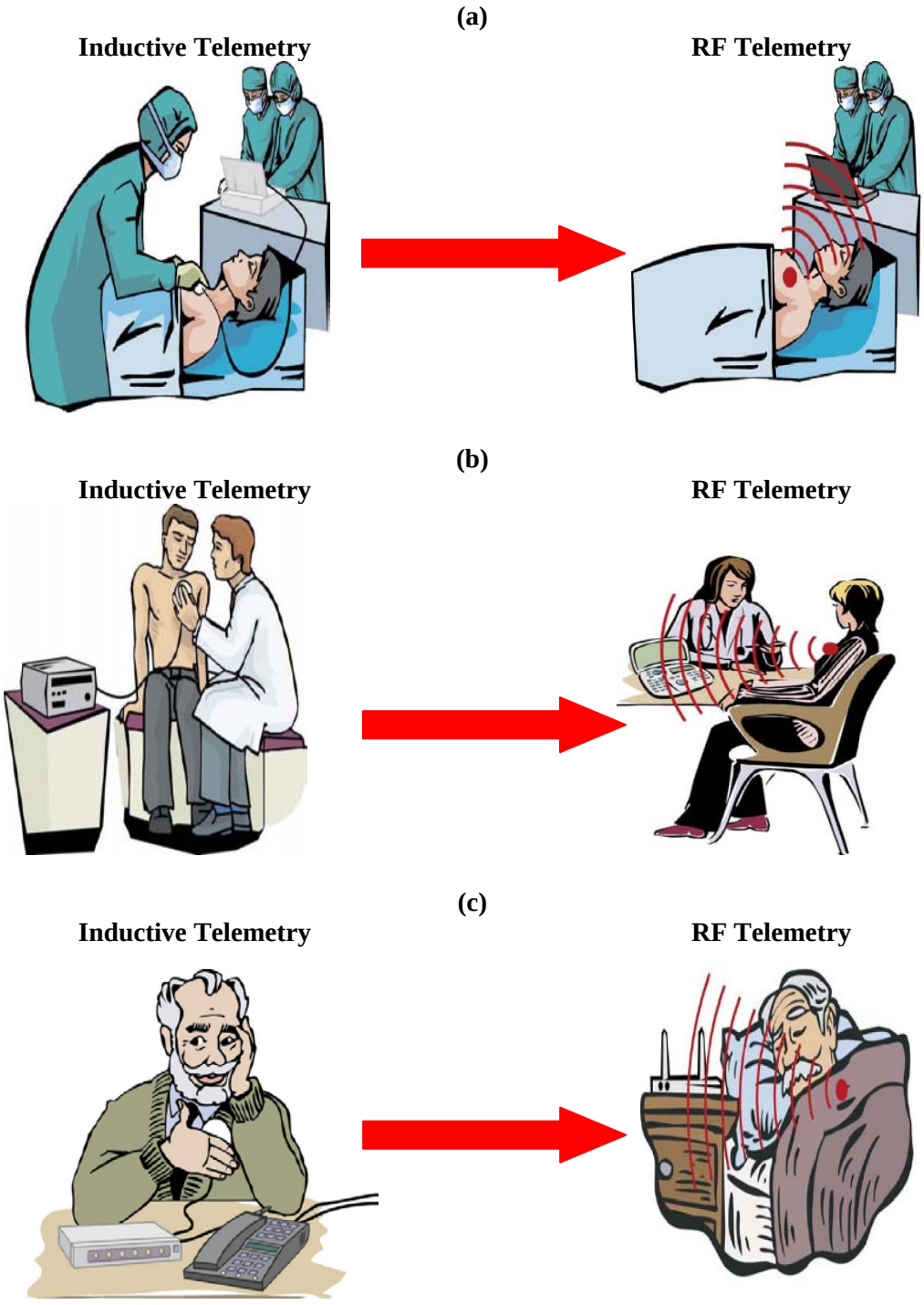


**Figure 6: Inductive Telemetry vs. RF Telemetry:**

**(a) – During/Post Surgery, (b) – Follow-up Clinics, (c) – Home Monitoring [7]**

The use of short-range inductive telemetry makes follow-up visits tedious and time-consuming, as it requires the health care provider to attend to each patient one by one. Even after establishing connection between the ICD and the base station, the patient has to stay still for a few minutes while the ICD is being interrogated or programmed as shown in Figure 6(b). The follow-up clinics need efficient ways for implanted device interrogation and programming to cover the increase in workload. RF telemetry can be used to start interrogating the implanted device remotely as soon as the patient arrives at the follow-up clinic to optimize patient flow and resource allocation. Sometimes these patients may not even make regular follow-up visits due to age or distance, and there is always the possibility that critical arrhythmic episodes can happen between follow-up visits. Some recent studies have shown that remote or home monitoring is being accepted as a replacement for time consuming and expensive visits to follow-up clinics [9]. Remote or home monitoring using inductive telemetry requires the patient to initiate monitoring session, and then the patient needs to hold the telemetry wand on the implant site for the entire duration of the monitoring session, while remote or home monitoring using RF telemetry is mostly automatic and is much more convenient than inductive telemetry as shown in Figure 6(c). Recently, all major ICD companies are providing wireless remote monitoring systems which are able to interrogate the ICD using RF telemetry. The periodic remote follow-up visits are conducted with the patient in their home within range of monitoring device and health care provider in the follow-up clinic. A remote monitoring system performs all the tests typically performed in the follow-up clinic, such as check battery status to find out battery life, measure lead impedance to verify lead integrity, measure sensing and capture thresholds to make sure that implanted device is sensitive enough to monitor heart rhythm, and retrieve diagnostic data to analyze disease progression. The data is then sent to the physician for review by landline phone or cellular network [8]. The remote monitoring system can also automatically perform implanted device interrogation on a daily basis, typically at night when patient is asleep as shown in Figure 6(c). It can then transmit the device status and device data over secure connections to the

physician's office for review. Lead fracture or dislocation, inappropriate shocks, and end of battery life are some of the causes which can compromise the function of an ICD. Consistent and more frequent monitoring can help us catch these problems before it is too late. These remote monitoring systems are mostly automatic and require minimal or no interaction from the patient. They are extremely easy to use and readily accepted by most of the patients. These systems are typically set up on the bedside table and perform automatic monitoring every night while the patient is asleep. For all these reasons remote monitoring has the potential to provide huge economic benefit, and convenience to both patient and health care provider while improving patient safety. As remote monitoring is slowly becoming more acceptable as a replacement for follow-up clinic visits, all major ICD manufacturers are providing remote monitoring systems as shown in Figure 7. Each of these systems depends on wireless communication using radio-frequency so that there is minimal patient compliance and involvement. Biotronik Cardiomessenger™ communicates wirelessly with the ICD within a radius of 2 meters and sends retrieved data to physician using a cellular phone network. It is a small device with a rechargeable battery so it can be carried around by the patient for round-the-clock monitoring. The St. Jude Medical Merlin@home™ communicates wirelessly with the ICD and sends retrieved data via landline phone. It also allows physicians to send alerts or reminders to the patient. Boston Scientific Latitude Patient Management™ also uses landline phone for data transmission and allows data transmission to different physicians which can potentially improve disease management. Medtronic Carelink™ communicates wirelessly with the implanted device within a radius of 3 meters and sends retrieved data to physician using a landline phone. It automatically performs a wide range of tests enabling full remote follow-up [8].

Biotronik Cardiomessenger™ mobile transmitter of the Home Monitoring system


St-Jude Medical Merlin@home™ wireless transmitter


Boston Scientific wireless transmitter, weight scale, and blood pressure monitor of the Latitude Patient Management™ system

Medtronic transmitter (Home Monitor) of the CareLink™ network

**Figure 7: Remote Monitoring Systems [8]**

# 2. Project Objective

The objective of this thesis is to implement the enhanced Medical Implant Communications Service (eMICS) algorithm. This algorithm is developed at St. Jude Medical for efficient and reliable connection with long range wireless communication for an ICD.

The Federal Communications Commission (FCC) regulates the use of the radio frequency spectrum. The FCC established the Medical Implant Communication Service (MICS) band in 1999 to provide an ultra-low power, mobile radio service for transmitting data in support of diagnostic or therapeutic functions associated with implanted and body-worn medical devices [10]. The MICS band operates from 402 to 405 MHz. These frequencies are conducive to transmitting radio signals in the human body and are compatible with international frequency allocations. The device using MICS band needs to make sure that there is no significant risk of interference to other radio operations in the band [11]. The MICS band is divided into 10 channels with 3 KHz band width for each channel as shown in Figure 8. Users of MICS band must cooperate in the selection and use of channels in order to reduce interference and to make the most effective use of the band. Each device using the MICS band must incorporate a mechanism for monitoring and selecting the channel(s) it intends to occupy to avoid interference to other transmissions ongoing by other implanted devices [12].

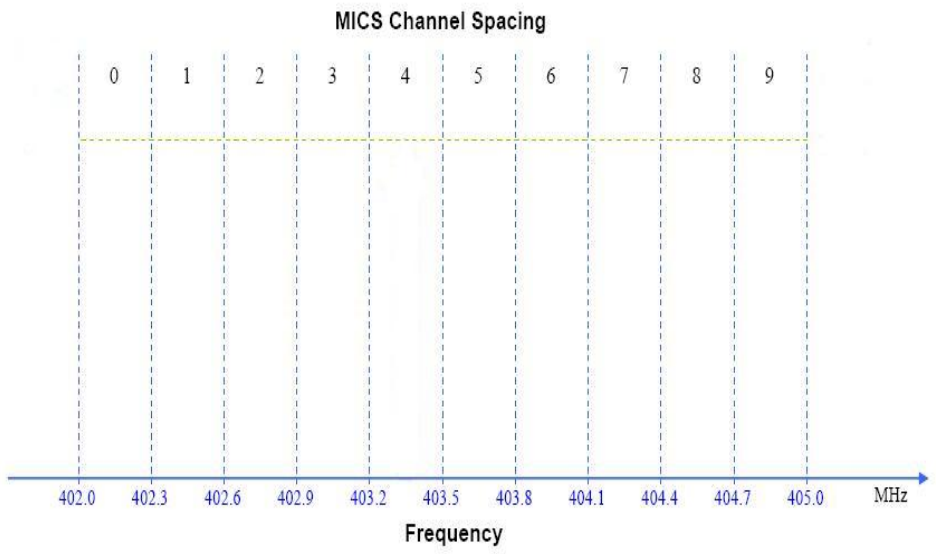


**Figure 8: MICS Channel Spacing**

The eMICS algorithm follows MICS standard "Listen Before Talk" (LBT) protocol and selects one of ten channels within the MICS band to establish a communication session. The RF transceiver in the ICD is kept in sleep mode until it is needed for communication with the base station. The goal is to implement a sniff based wakeup scheme which periodically wakes up the RF transceiver to perform energy sniff in the MICS band and establish a communication session between the ICD and the base station. The St. Jude Medical ICD already supports a 2.45 GHz band based asynchronized wakeup and 400 MHz (MICS) band based synchronized wakeup. The 2.45 GHz band base asynchronized wakeup uses 2.45 GHz band to wakeup the RF transceiver in the ICD and then switches to 400 MHz band for communication. This scheme is asynchronized so the ICD is always listening for base station's request for wakeup and communication can be established anytime. The MICS band based synchronized wakeup uses 400 MHz band to wakeup the RF transceiver as well as for communication. This scheme is synchronized so the ICD listens to the base station's request for wakeup periodically. The base station can wakeup the ICD and establish communication only at a predefined time (typically every 2 hours when the ICD is listening for wakeup request from the base station). However, there are drawbacks for both these wakeup schemes. The 2.45 GHz band based asynchronized wakeup has limited wakeup range

(around 2-6 feet) between the ICD and base station. Therefore, this wakeup scheme fails to wakeup the ICD for around 5-10% of the cases when ICD is implanted deep under the skin and tissue. The MICS based synchronized wakeup have longer range (around 20-30 feet) but the attempt for synchronized connection with the base station every 2 hours presents significant drawback on availability for connection. If the connection attempt fails due to the ICD and the base station being out of range or for any other reason then the next connection can only be established after predefined time duration has elapsed. Also there are chances of losing synchronization between the ICD and the base station due to device firmware reset or base station system reset. Some of the reasons for the device firmware reset are, but not limited to, software glitch, magnetic interference etc. Some of the reasons for the base station system reset are, but not limited to, software glitch, power outage etc. In such cases the ICD and the base station have to be resynchronized, and there is a risk of losing critical patient monitoring data. The eMICS is a purely firmware based solution implemented on the Unity device platform for ICD. Like MICS band based synchronized wakeup it uses 400 MHz band for wakeup and addresses the wakeup range limitation in 2.45 GHz band based asynchronized wakeup. Since the ICD is sniffing for energy is MICS band every 60-90 seconds, it provides many opportunities to establish a communication channel between the ICD and the base station than the MICS band based synchronized wakeup. This algorithm provides fast, robust, and seamless wakeup and communication using MICS band.

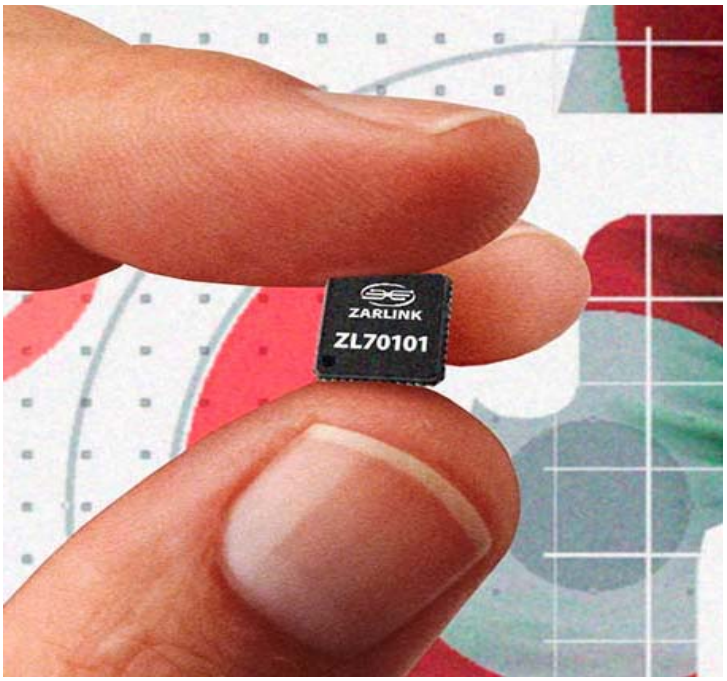


**Figure 9: Zarlink Semiconductor Inc.'s ZL70101 RF Transceiver Chip [7]**

St. Jude Medical's ICD uses Zarlink Semiconductor Inc.'s ZL70101 medical implant transceiver chip which is shown in Figure 9. The ZL70101 Medical Implant RF Transceiver is an ultra low power chip that provides high speed communications between the Implantable Medical Device (IMD) and an external device over the MICS band. The chip can be configured in two different modes, IMD mode and Base mode. While in IMD mode it has ultra low power consumption: 250nA during sleep state and around 5mA during wakeup state, which is vital for longer battery life in an implanted device [13]. While in Base mode the ultra low power consumption is normally not a constraint as the base station is connected to a power outlet.

**(a)**


**(b)**


**Figure 10: Base Station: (a) – Merlin™ Patient Care System, (b) – Merlin@Home™ Transmitter System**

The base station is an RF-enabled external device. Figure 10(a) shows St. Jude Medical's Merlin™ Patient Care System and Figure 10(b) shows the Merlin@Home™ Transmitter System. The ZL70101 medical implant transceiver chip is configured in Base mode for the base station. The Merlin™ Patient Care System allows programming at the time of the implant as well as during the patient's follow-up visits. It has a longer communication range of a few feet which provides freedom of movement in the operating room. During follow-up visits the ICD can be interrogated remotely as soon as the patient arrives at the clinic and is waiting in the waiting room to manage patient flow efficiently. The Merlin@Home™ transmitter system allows remote patient monitoring and follow-ups. The transmitter can be set-up wherever a standard phone line is available, typically by the bedside for communication while the patient sleeps. It collects nightly diagnostic readings from the ICD and securely transmits the data to the physician's office.

During scheduled follow-ups, the patient does not need to travel to the follow-up clinic; he/she just has to remain within the range of the transmitter.

For the eMICS algorithm, firmware commands the wakeup of the ZL70101 chip in the ICD on a prescheduled basis (every 60-90 seconds) throughout the life of ICD. During each such wakeup, the ICD sniffs energy in the MICS band to check if there is any base station request for connection. The ICD goes back to low power sleep mode if no base station request is sensed. If there is a base station request found, the ICD tries to match the device identification number found in the MICS band with its own device identification number. If there is a match then the ICD attempts a connection with the base station and connection is established upon completion of a handshake from the base station. Once the base station is connected to the ICD, the base station can program the ICD and retrieve data from the ICD.

In the operating room, recovery room, and follow-up clinics the health care provider can use the Merlin™ Patient Care System to initiate a connection with a specific ICD by programming the proper device identification number. The Merlin@Home™ transmitter system is programmed with the proper device identification number in the hospital before the patient brings it home and sets it up on the bedside table. The home monitor is programmed to initiate communication with the ICD at a specific time; typically during the night while the patient is asleep. The objective is to implement an efficient wakeup algorithm with frequent energy sniffs with efficient sniff duration while reducing the occurrences of false wakeups to have minimal impact on the battery longevity and on the other firmware algorithms running in the commercially available St. Jude Medical ICD. The frequent sniff interval is essential to provide as many chances as possible for a successful connection with the base station. The shorter sniff duration is essential to reduce the duration when the RF transceiver is in wakeup state drawing around 5mA current. Reducing occurrences of false wakeups is essential to avoid waking up the RF transceiver when there is no potential successful connection with the base station. If the ICD is in noisy environment, excessive false wakeups could adversely affect the battery life as well as

other critical and time sensitive algorithms in the ICD which monitors heart rhythm and delivers electrical jolt when needed.

# 3. Design and Implementation

The eMICS feature is broken up into sub-features; wakeup scheme, false wakeup avoidance and emergency wakeup. The wakeup scheme feature handles when to wakeup the ZL70101 chip, sniff the MICS band, and try to establish communication session with the base station. The false wakeup avoidance feature tries to minimize false wakeups in a noisy environment by adjusting the energy threshold used during energy sniff. The emergency wakeup feature allows the ICD to initiate a communication with the base station for critical events and alerts. This thesis focuses on the design, implementation, and initial testing of the eMICS feature during the Technology Project Management (TPM) phase. The main focus during the TPM phase is to provide the initial version of the algorithm, mitigate major risks, and provide feasibility details. After the TPM phase, the algorithm and code base is transferred to the Product Project Management (PPM) phase, where it goes through thorough verification and validation testing before it is released as a commercially available product.

The role of a software engineer at St. Jude Medical in this thesis was to participate in the design, implementation and initial testing of the eMICS algorithm. This also included using knowledge of the Unity device platform and performing integration testing to verify that the eMICS feature code does not cause any interference in already existing ICD features' functionality. During the design phase, firmware engineers defined interfaces to other features and Unity architecture as well as identified pieces of code which needs to be modified. After the design phase, firmware engineers implemented the algorithm and performed bench testing. An automated test tool developed at St. Jude Medical was used to test wakeup scheme and false wakeup avoidance efficiently. This test tool helped firmware engineers to test the reliability of the wakeup scheme and also analyze occurrences of false wakeups. The test tool was also used to characterize the feature functionality in home and clinic settings. Firmware engineers used the tool to perform tests at their home, and clinical engineers used the tool to perform tests in

hospitals and follow-up clinics as described later. The test results helped the team tremendously in fine tuning and improving the algorithm. The next sub-sections describe the design for each eMICS sub-feature. Firmware engineers used these designs to implement the features in C code.

## *3.1 Wakeup scheme*

### For the base station

Removed by St. Jude Medical legal.

### For the ICD

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## *3.2 False Wakeup Avoidance*

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## *3.3 Emergency Wakeup*

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# 4. Testing and Results

The eMICS algorithm was tested under a controlled lab environment, typical home environment, typical hospital/clinic environment, and in the field. There were two matrix criteria for this testing; connection reliability and false wakeup likelihood. The ICDs were embedded in a gel box to simulate the amount of attenuation present with the implanted device in a human body. The ICDs were scheduled to wakeup every 16 seconds instead of typical 60-90 seconds setting for quicker test runs. The value of *Sniff Threshold* was set to a high value of 30 counts to see the performance of the Sniff Threshold Auto-tuning algorithm. The value of the *Allowed False Wakeups* was programmed to 10 counts instead of typical value of 2-3 counts so that the timer with duration equal to the *Sniff Interval* was not disabled too quickly when there were occurrences of false wakeups. Testing in the lab environment and typical home environment was performed by firmware engineers. Testing in typical hospital/clinic environments was performed by clinical engineers.

The eMICS automated test tool was developed at St. Jude Medical to assist firmware and clinical engineers in these testing efforts. The tool runs on a laptop which is connected to the Digital Telemetry Module (DTM) box via serial port. The DTM box is manufactured at St. Jude Medical for internal use. It is used to communicate between the ICD and the base station via inductive telemetry. The DTM box has a connection for an inductive telemetry wand and is controlled by the test tool. The RF telemetry wand is directly connected to the laptop via USB and is controlled by the test tool. Engineers have to perform a few simple steps to setup the tool for test runs.

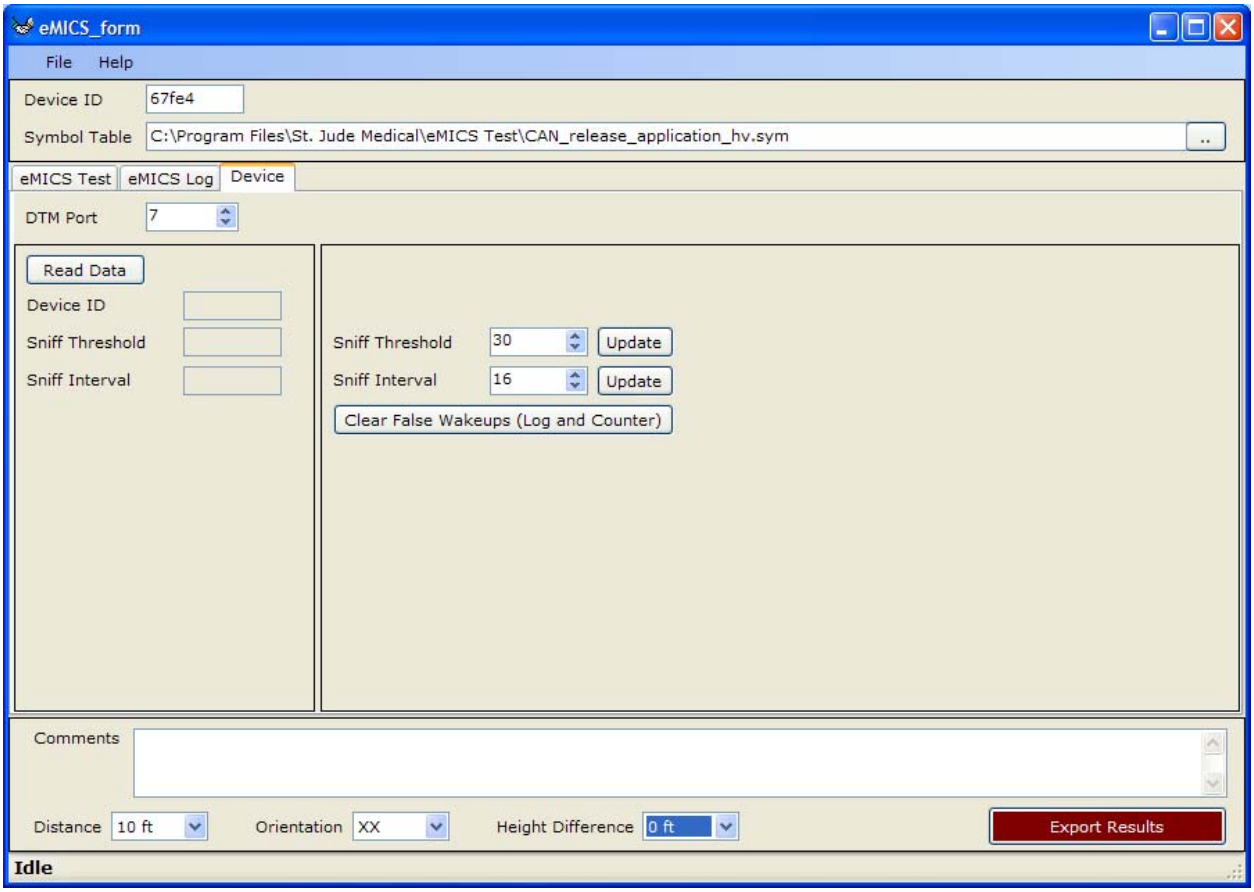


**Figure 11: eMICS Automated Test Tool - ICD Programming**

Figure 11 shows the ICD Programming screen. The engineer needs to specify the device identification number, the port to which the DTM box is connected, the initial value for *Sniff Threshold*, and the initial value for *Sniff Interval* on this screen. The test tool uses device identification number to identify the ICD and programs the ICD using inductive telemetry when the "Update" button(s) is clicked. The engineer can read data back from the ICD by clicking "Read Data" button to verify the ICD programming. The engineer also needs to clear the test log and the *False Wakeup Counter* for a clean test run by clicking the "Clear False Wakeups (Log and Counter)" button.

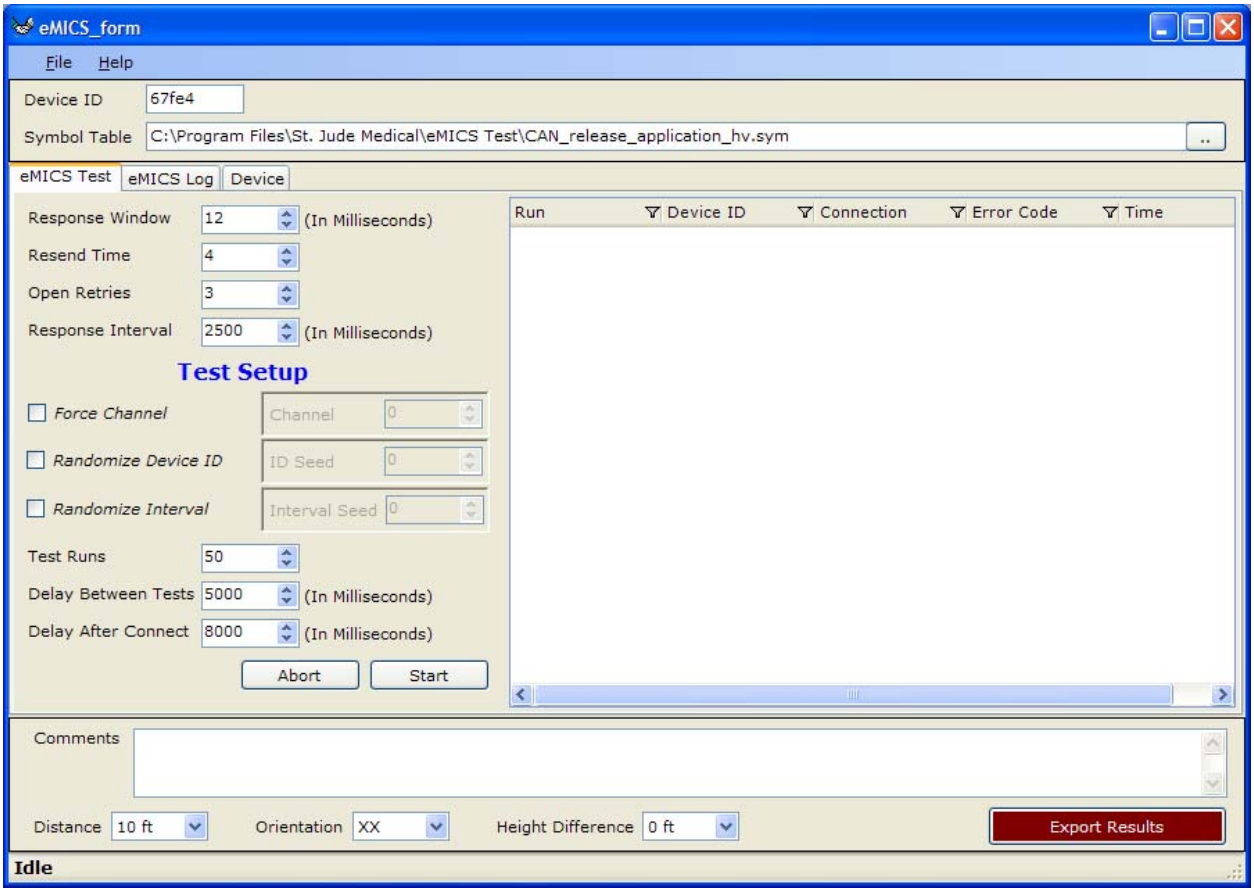


**Figure 12: eMICS Automated Test Tool - Test Run Setup**

After programming the ICD, the engineer needs to specify the test run details on the Test Run Setup screen as shown in Figure 12. The tool allows the engineer to use different combinations of programmable parameters. For this initial testing, the value of the *Response Interval* is set to 2500ms, the value of the *Response Window* is set to 12ms, the value of the *Resend Time* is set to 4, and the value of the *Open Retry* is set to 3. The force Channel, The randomize Device ID, and Randomize Interval options were not used for this initial testing. Force Channel option lets the user specify a specific channel to transmit wakeup packets. Randomized Device ID option uses ID seed to generate a random device identification number which is transmitted in wakeup packets. The randomize Interval option uses Interval Seed to generate a random interval value which is used as Response Interval. The engineer needs to specify how many tests to run in each test run, the time duration the tool should wait between tests, and the

time duration the tool should wait after establishing a connection link between the base station and the ICD. He/She also needs to specify the distance, orientation, and height difference between the ICD and the base station. The engineer is encouraged to specify comments related to test setup in the comment section. The comment section is mainly used during home testing, clinic testing, and field testing to specify additional environment information. He/She can start the test run by clicking the “Start” button.

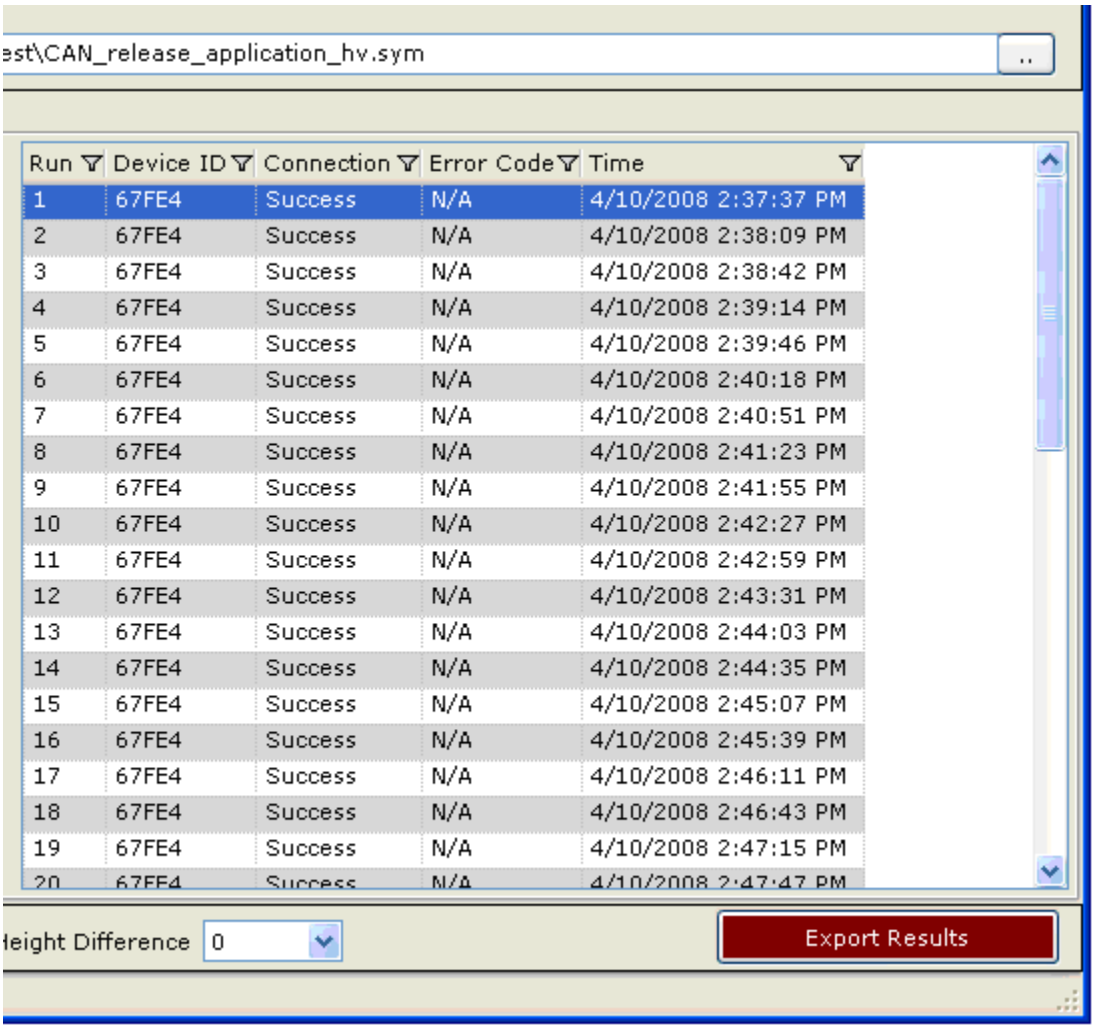


**Figure 13: eMICS Automated Test Tool - Test Log**

During the test run, the test tool keeps track of results from each individual test and updates the Test Log screen. Figure 13 shows an instance of a test log. The “Run” column indicates the test number in a run. The “Device ID” column indicates the device identification

number of the ICD. The “Connection” column indicates whether the connection was successful or unsuccessful. The “Error Code” column indicates the error code in cases where connection was unsuccessful. The “Time” column indicates the time when connection was attempted.

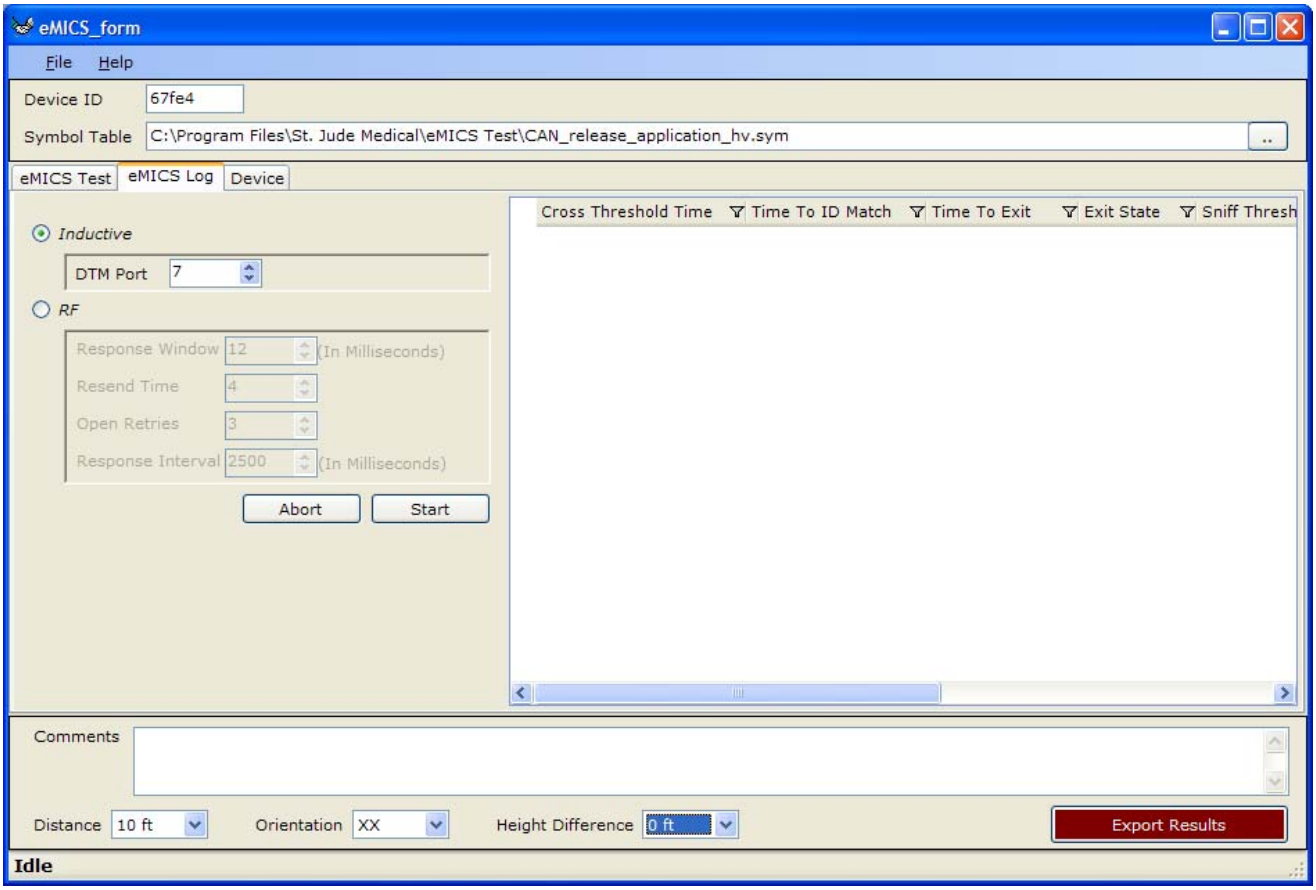


**Figure 14: eMICS Automated Test Tool - Retrieve eMICS Log**

The ICD with a special version of firmware captures the log through out the test run. The code which goes in a production device which is shipped for human use does not contain firmware with log capture capabilities. Figure 14 shows the Retrieve eMICS log screen. After the test run is over, the engineer can use either inductive telemetry or RF telemetry to retrieve these logs from the ICD using this screen.

| Cross Threshold Time | Time To ID Match | Time To Exit | Exit State | Sniff Threshold Value | Channel | False Wakeup Count | ID Found |
|---|---|---|---|---|---|---|---|
| 4/10/2008 2:37:56 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 8 | 0 | TRUE |
| 4/10/2008 2:38:28 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:39:00 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 1 | 0 | TRUE |
| 4/10/2008 2:39:32 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:40:04 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 3 | 0 | TRUE |
| 4/10/2008 2:40:36 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:41:08 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:41:40 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:42:12 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 9 | 0 | TRUE |
| 4/10/2008 2:42:44 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:43:16 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:43:48 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:44:20 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:44:52 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 2 | 0 | TRUE |
| 4/10/2008 2:45:24 PM | 0 | 2000 | STATE_400_CONNECT | 14 | 3 | 0 | TRUE |

**Figure 15: eMICS Log**

Figure 15 shows an instance of an eMICS log retrieved from the ICD. The “Cross Threshold Time” column indicates the time when the energy level greater than the value of the *Sniff Threshold* was measured in MICS band. The “Time to ID Match” indicates the number of microseconds it took for the ICD to find a matching device identification number. The “Time to Exit” indicates the number of microseconds the ICD was waiting after sending the *‘Link Ready’* message and before receiving the *‘Connect Confirm’* message from the base station. The “Exit State” column indicates the last state of the algorithm upon success or failure of the connection attempt. The “Sniff Threshold Value” column indicates the value of the *Sniff Threshold* being used by the algorithm during connection attempt. The “Channel” indicates the MICS channel being used during connection attempt. The “False Wakeup Count” column indicates the number of false wakeups recorded by the device. The “ID Found” column indicates whether the matching device identification was found or not. The engineer can export the test log and the eMICS log to

an Excel spreadsheet for further investigation and analysis by clicking the “Export Results” button.

This automated test tool helps engineers tremendously. The tool provides a mechanism to execute test runs reliably and repeatedly. It frees up the engineers to perform other tasks while the test run is in progress. The tool also helps in streamlining the testing since each engineer is provided with the instructions on how to use the tool and the test protocol to follow in different settings.

## *4.1 Lab Testing*

During the Lab Testing, firmware engineers tried to cover different ICD and base station settings. The distance tests were performed to simulate a patient near or far from the base station. The orientation tests were performed to simulate the different patient positions with respect to the base station. The height tests were performed to simulate variation in patient height, or patient sitting/standing near the base station.

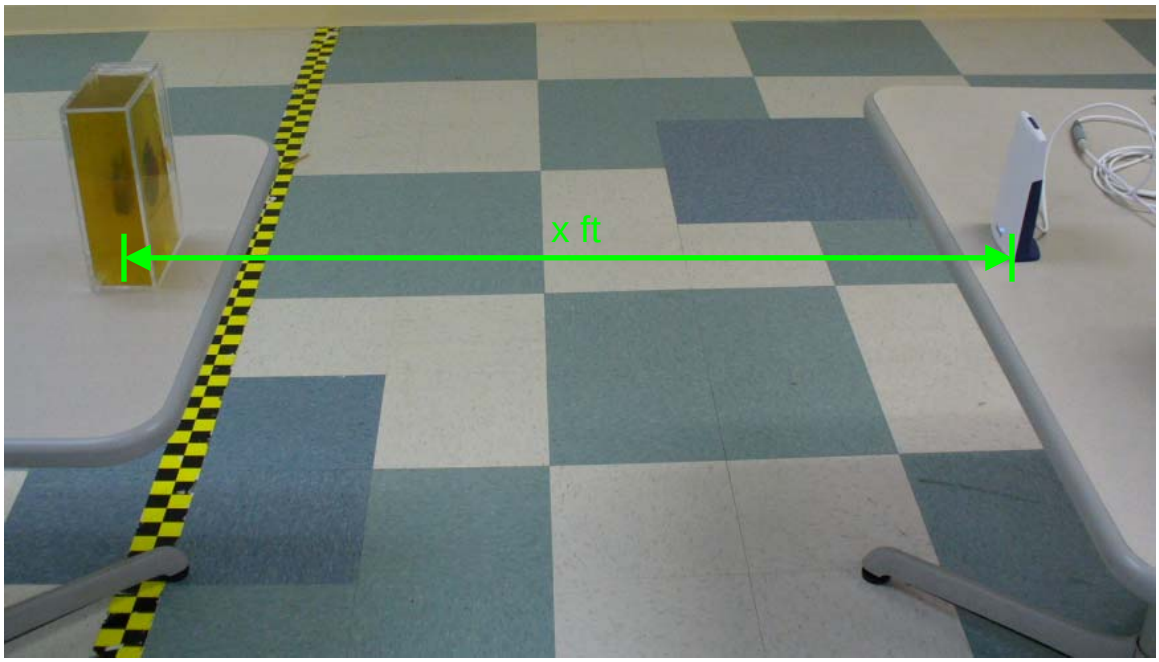


**Figure 16: Distance Test**

For the Distance Test, the base station and the ICD in a gel box were setup at various distances ranging from 5 ft through 30 ft apart with 5 ft increments as shown in Figure 16. During these test runs the base station and the ICD in a gel box were facing each other and were on the same level. The test run consisted of 50 tests for 5 ft, 10 ft, and 15 ft distances and 10 tests for 20 ft, 25 ft and 30 ft distances.

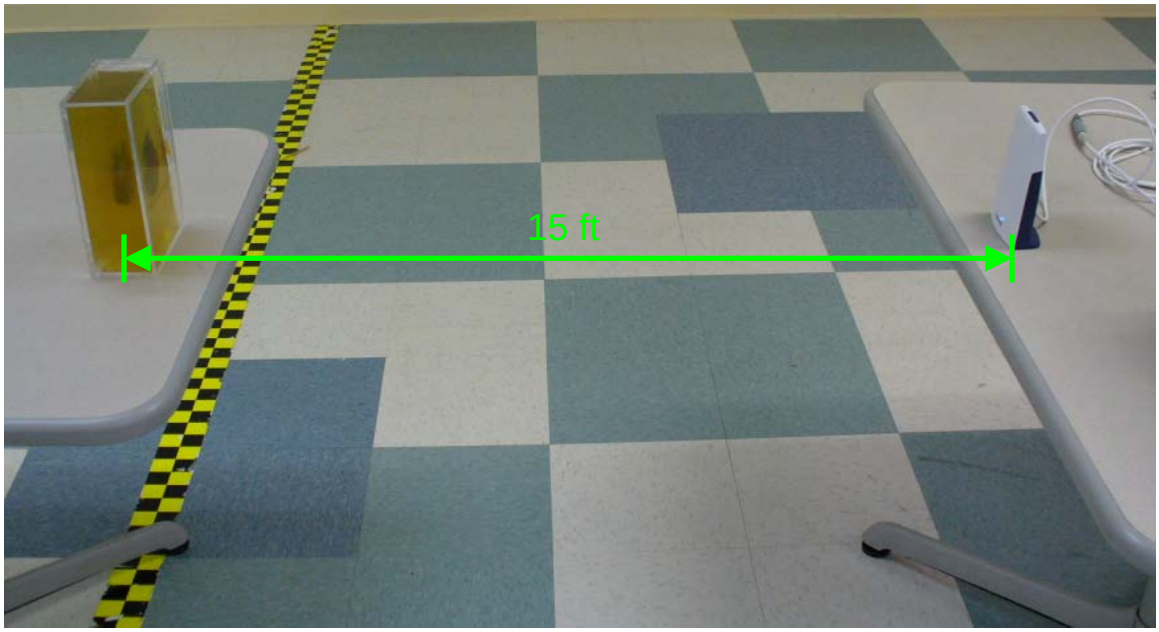


**Figure 17: XX Orientation Test**

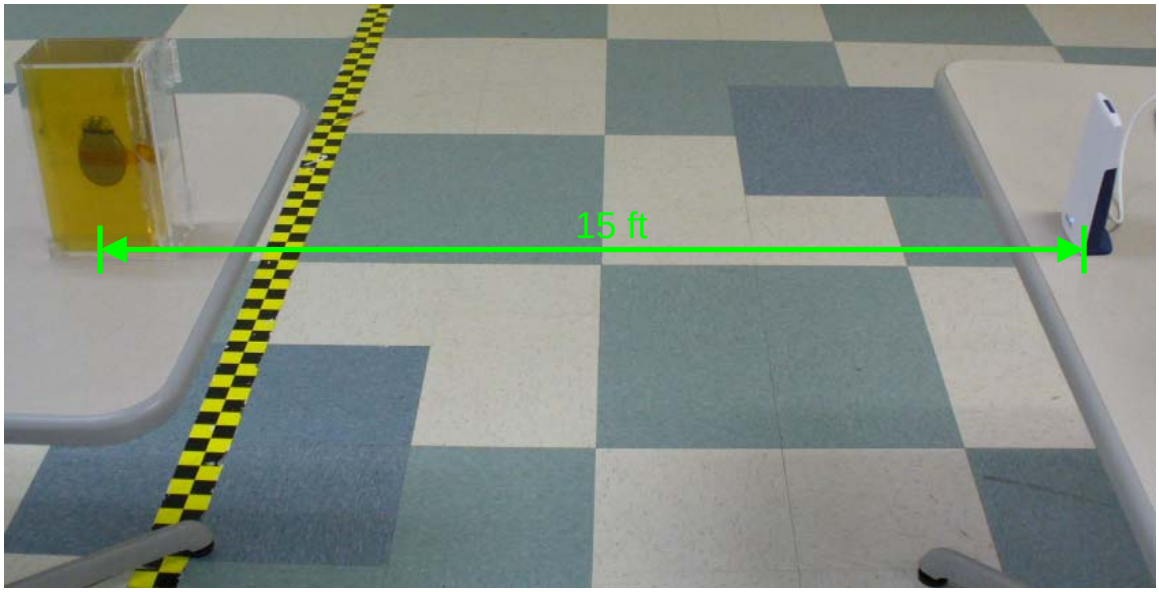


**Figure 18: XY Orientation Test**

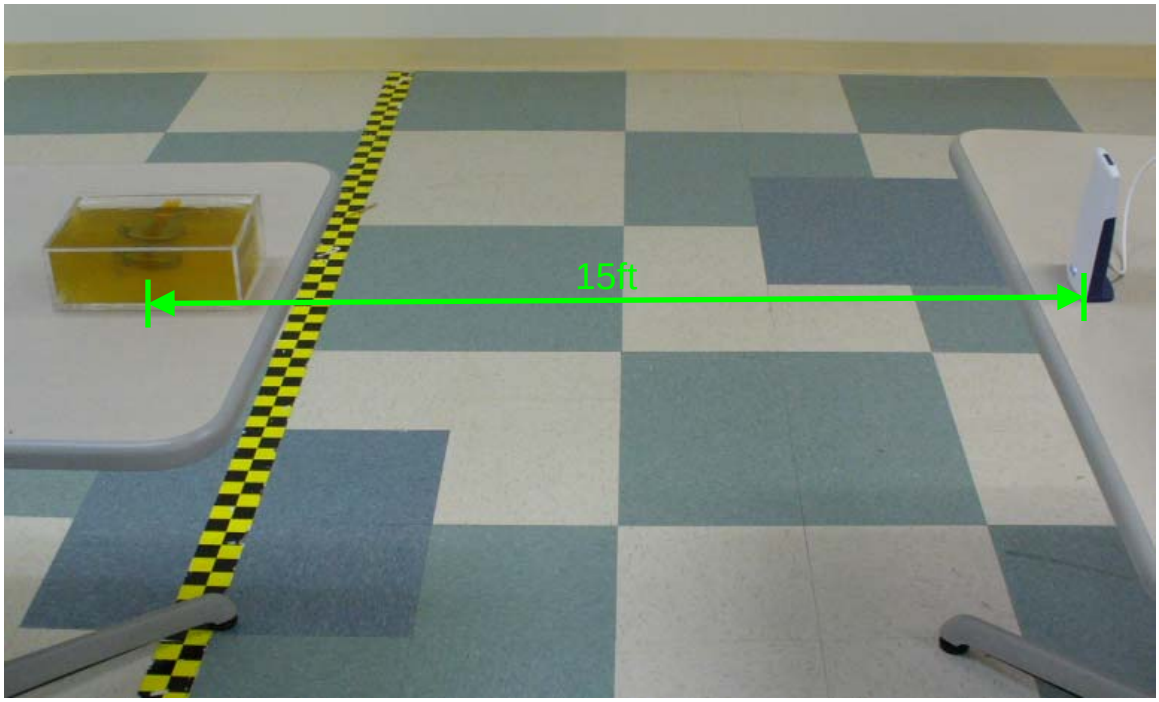


**Figure 19: XZ Orientation Test**

For the Orientation Test, the base station and the ICD in a gel box were placed facing each other at the same level 15 ft apart for XX orientation test run as shown in Figure 17. Then the gel box was rotated such that the ICD was perpendicular to base station at 15 ft distance for XY orientation test run as shown in Figure 18. Eventually the gel box was placed flat on the surface so that the ICD was lying flat with respect to the base station at a 15 ft distance for XZ orientation test run as shown in Figure 19. All orientation test runs consisted of 10 tests.

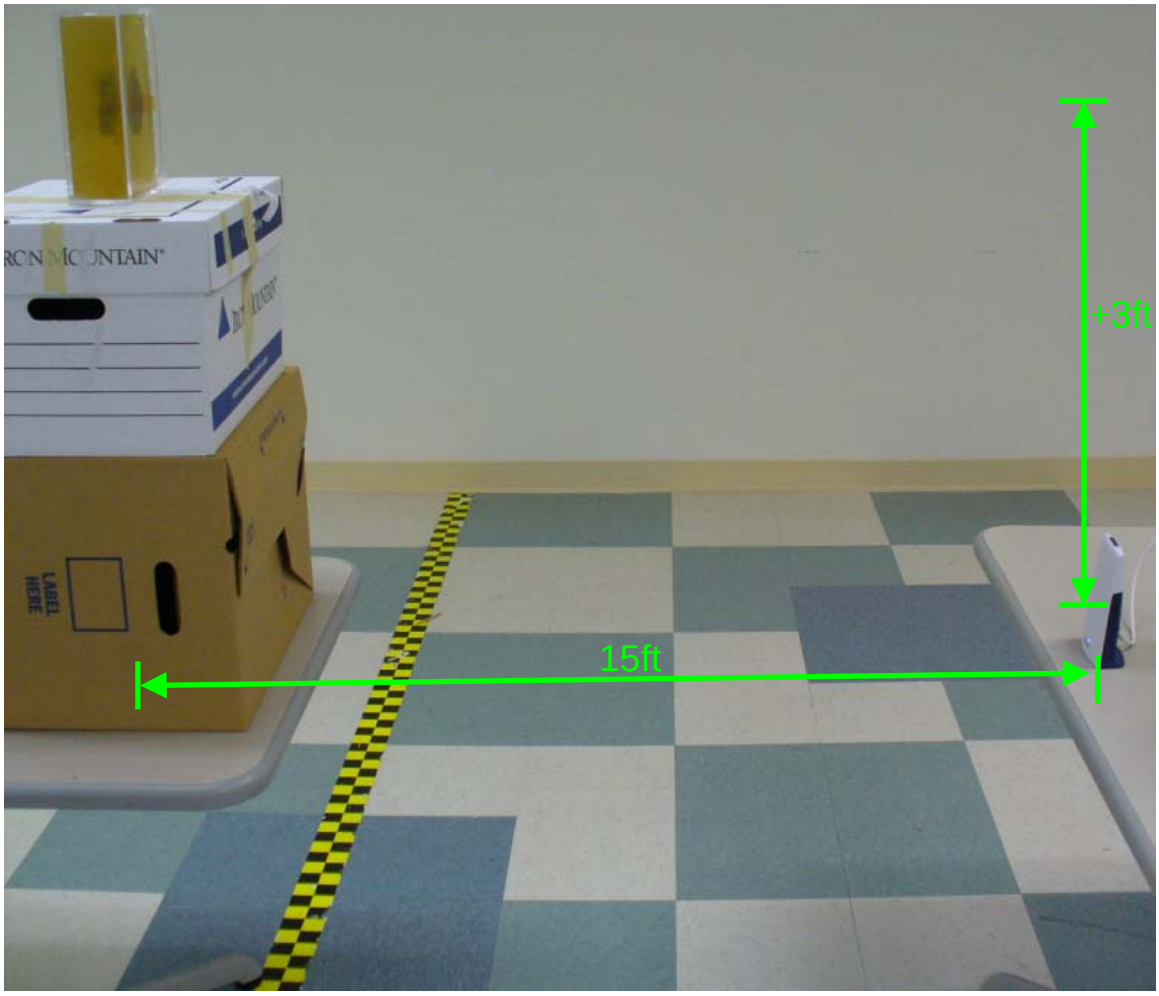


**Figure 20: +3 Height Test**

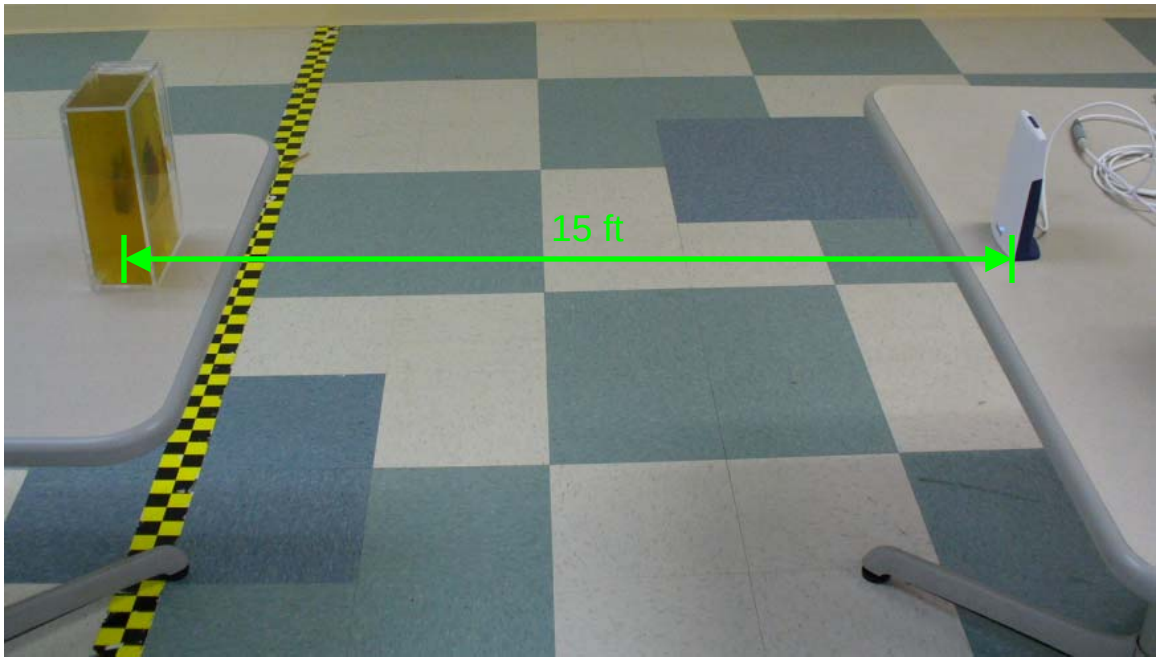


**Figure 21: 0 Height Test**

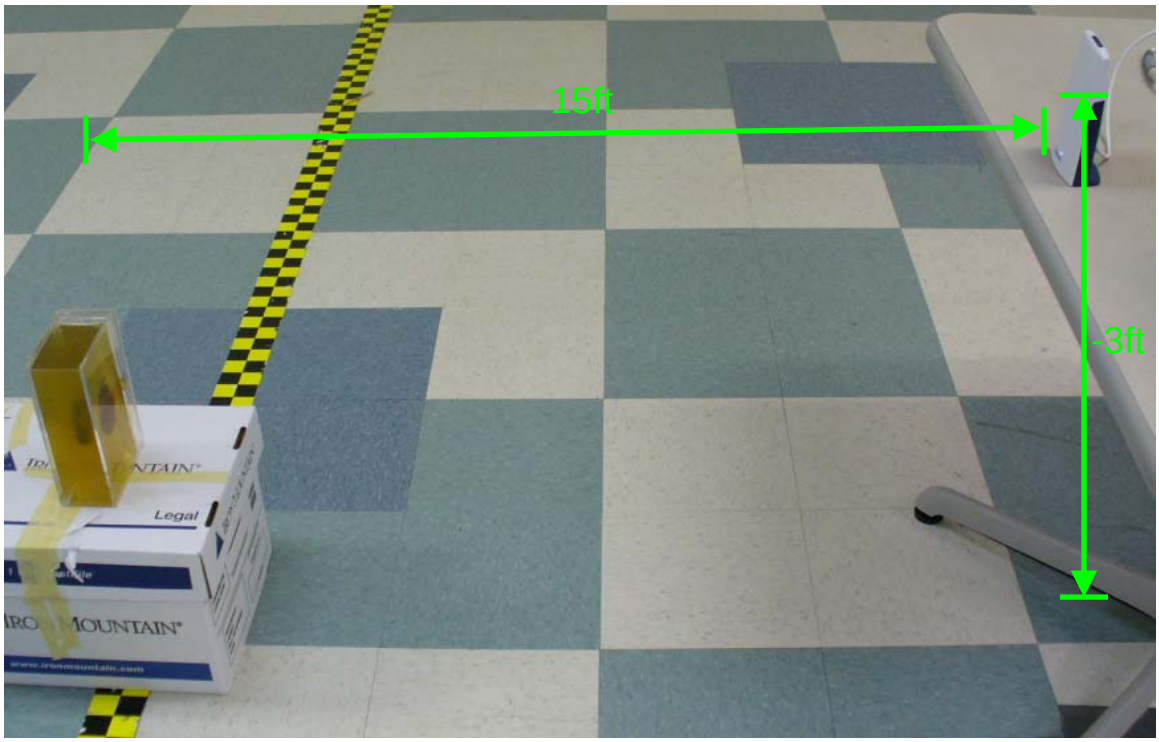


**Figure 22: -3 Height Test**

For the Height Test, the base station and the ICD in a gel box were placed such that they were facing each other, and the ICD was 3 ft higher than the base station at 15 ft distance for a

+3ft height test run as shown in Figure 20. Then the gel box was moved such that the ICD and the base station were at the same level 15 ft apart for a 0ft height test run as shown in Figure 21. Eventually the gel box was placed such that the ICD was 3 ft lower than base station at a 15 ft distance for a -3ft height test run as shown in Figure 22. All height test runs consisted of 10 tests.

## Results:

Eight different ICDs were used during the Lab Testing. The test environment was kept as identical as possible to avoid external interference like obstruction of signals due to movement of objects in the lab, noise from use of other machines/instruments, etc. There were no false wakeups recorded in the Lab Testing. The Sniff Threshold Auto-Tuning algorithm worked very well, and the *Sniff Threshold* was quickly adjusted to a value between 14 and 18 counts – a nominal energy value found in MICS band during wakeup packet transmission in an environment without other interferences.

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 50 | 49 | 98 | 31370 |
| 50 | 45 | 90 | 66ded |
| 50 | 49 | 98 | 66ea4 |
| 50 | 46 | 92 | 674e1 |
| 50 | 50 | 100 | 67feb |
| 50 | 43 | 86 | 64750 |
| 50 | 42 | 84 | 67fe4 |
| 50 | 47 | 94 | 621ab |
| Average Connection Rate: 92.75% | | | |

**Table 1: Distance Test: 5ft Test Results**

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 50 | 49 | 98 | 31370 |
| 50 | 48 | 96 | 66ded |
| 50 | 48 | 96 | 66ea4 |
| 50 | 50 | 100 | 674e1 |
| 50 | 50 | 100 | 67feb |
| 50 | 48 | 96 | 64750 |
| 50 | 46 | 92 | 67fe4 |
| 50 | 49 | 98 | 621ab |
| Average Connection Rate: 97% | | | |

**Table 2: Distance Test - 10ft Test Results**

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 50 | 44 | 88 | 31370 |
| 50 | 40 | 80 | 66ded |
| 50 | 48 | 96 | 66ea4 |
| 50 | 50 | 100 | 674e1 |
| 50 | 50 | 100 | 67feb |
| 50 | 42 | 84 | 64750 |
| 50 | 46 | 92 | 67fe4 |
| 50 | 48 | 96 | 621ab |
| Average Connection Rate: 92% | | | |

**Table 3: Distance Test: 15ft Test Results**

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 10 | 9 | 90 | 31370 |
| 10 | 9 | 90 | 66ded |
| 10 | 9 | 90 | 66ea4 |
| 10 | 9 | 90 | 674e1 |
| 10 | 8 | 80 | 67feb |
| 10 | 10 | 100 | 64750 |
| 10 | 8 | 80 | 67fe4 |
| 10 | 8 | 80 | 621ab |
| Average Connection Rate: 87.5% | | | |

**Table 4: Distance Test: 20ft Test Results**

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 10 | 8 | 80 | 31370 |
| 10 | 7 | 70 | 66ded |
| 10 | 9 | 90 | 66ea4 |
| 10 | 9 | 90 | 674e1 |
| 10 | 7 | 70 | 67feb |
| 10 | 7 | 70 | 64750 |
| 10 | 9 | 90 | 67fe4 |
| 10 | 9 | 90 | 621ab |
| Average Connection Rate: 81.25% | | | |

**Table 5: Distance Test: 25ft Test Results**

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 10 | 9 | 90 | 31370 |
| 10 | 9 | 90 | 66ded |
| 10 | 10 | 100 | 66ea4 |
| 10 | 8 | 80 | 674e1 |
| 10 | 7 | 70 | 67feb |
| 70 | 7 | 70 | 64750 |
| 70 | 8 | 80 | 67fe4 |
| 10 | 8 | 80 | 621ab |
| Average Connection Rate: 82.5% | | | |

**Table 6: Distance Test: 30ft Test Results**

The average connection rate between the ICD and base station was greater than 90% for 5 ft, 10 ft and 15 ft distances as shown in Table 1, Table 2 and Table 3 respectively. It was greater than 80% for 20 ft, 25 ft and 30 ft distances as shown in Table 4, Table 5 and Table 6 respectively. The decrease in the average connection rate over longer distances was expected due to decrease in signal strength over longer distances.

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 10 | 7 | 70 | 31370 |
| 10 | 10 | 100 | 66ded |
| 10 | 9 | 90 | 66ea4 |
| 10 | 10 | 100 | 674e1 |
| 10 | 10 | 100 | 67feb |
| 10 | 9 | 90 | 64750 |
| 10 | 9 | 90 | 67fe4 |
| 10 | 10 | 100 | 621ab |
| Average Connection Rate: 92.5% | | | |

**Table 7: Orientation Test: XX Orientation Test Results**

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 10 | 7 | 70 | 31370 |
| 10 | 7 | 70 | 66ded |
| 10 | 10 | 100 | 66ea4 |
| 10 | 9 | 90 | 674e1 |
| 10 | 10 | 100 | 67feb |
| 10 | 8 | 80 | 64750 |
| 10 | 6 | 60 | 67fe4 |
| 10 | 8 | 80 | 621ab |
| Average Connection Rate: 81.25% | | | |

**Table 8: Orientation Test: XY Orientation Test Results**

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 10 | 10 | 100 | 31370 |
| 10 | 7 | 70 | 66ded |
| 10 | 10 | 100 | 66ea4 |
| 10 | 9 | 90 | 674e1 |
| 10 | 6 | 60 | 67feb |
| 10 | 8 | 80 | 64750 |
| 10 | 8 | 80 | 67fe4 |
| 10 | 8 | 80 | 621ab |
| Average Connection Rate: 82.5% | | | |

**Table 9: Orientation Test: XZ Orientation Test Results**

The average connection rate for the XX orientation was greater than 90% as shown in Table 7 while the same was greater than 80% for XY and XZ orientation as shown in Table 8 and Table 9 respectively. The slight decrease in the connection rate for XY and XZ orientation might

be due to the placement of the antenna in the ICD or due to the design of the metal housing for the ICD. However, it can not be deduced with certainty with this small set of test results.

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 10 | 10 | 100 | 31370 |
| 10 | 9 | 90 | 66ded |
| 10 | 10 | 100 | 66ea4 |
| 10 | 9 | 90 | 674e1 |
| 10 | 9 | 90 | 67feb |
| 10 | 9 | 90 | 64750 |
| 10 | 8 | 80 | 67fe4 |
| 10 | 9 | 90 | 621ab |
| Average Connection Rate: 91.25% | | | |

**Table 10: Height Test: +3ft Height Test Results**

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 10 | 8 | 80 | 31370 |
| 10 | 10 | 100 | 66ded |
| 10 | 9 | 90 | 66ea4 |
| 10 | 10 | 100 | 674e1 |
| 10 | 10 | 100 | 67feb |
| 10 | 9 | 90 | 64750 |
| 10 | 9 | 90 | 67fe4 |
| 10 | 8 | 80 | 621ab |
| Average Connection Rate: 91.25% | | | |

**Table 11: Height Test: 0ft Height Test Results**

| Connection Attempts | Connection Success | Connection % | Device |
|---|---|---|---|
| 10 | 10 | 100 | 31370 |
| 10 | 9 | 90 | 66ded |
| 10 | 10 | 100 | 66ea4 |
| 10 | 9 | 90 | 674e1 |
| 10 | 9 | 90 | 67feb |
| 10 | 9 | 90 | 64750 |
| 10 | 8 | 80 | 67fe4 |
| 10 | 10 | 100 | 621ab |
| Average Connection Rate: 92.5% | | | |

**Table 12: Height Test: -3ft Height Test Results**

For all Height test runs, the average connection rate was greater than 90% as shown in Table 10, Table 11 and Table 12. It was noticed that if the ICD and the base station were placed

closer than 15 ft, there was a slight reduction in connection rate, which might be due to the characteristics of the antenna design. However, large scale thorough testing is required to conclude it with certainty.

## *4.2 Home Testing*

Five firmware engineers performed the Home testing in their homes. Some homes were apartments while some were single family homes. The location of the homes, floor plans, room sizes, etc. varied from one home to another. There were some electronics which were common in all homes such as TV, microwave oven, cordless phones, cell phones, etc. while there were some electronics which were only present in one or two homes such as security systems, remote controlled toys, and short range walkie talkies, etc.

For the Bedroom Test, the ICD in a gel box was placed in the bedroom such that the ICD was lying flat and the base station was placed around a 5-8 ft distance from the ICD to simulate the patient lying on the bed and the base station situated somewhere in the bedroom. Typically the base station was placed on the bedside table and most of the time it is less than 5ft in distance from the ICD. The test run consisted of 30 tests. The tester was encouraged to use regular home electronics such as a TV, CD player, microwave oven, hair dryer, cell phone, cordless phone, etc and log the exact condition under which the test was performed.

For the Living Room Test, the ICD in a gel box was placed upright between the kitchen and living room during an evening to simulate the patient spending time in the kitchen or living room having dinner, watching television etc. The test run consisted of 30 tests. Due the sizes of rooms, the distance between the ICD and the base station varied, so the tester was asked to log the distances along with the test conditions such as which home electronics were on and how frequently people moved around, etc.

For Across Room Test, the ICD in a gel box and the base station were placed in different rooms where there were obstacles such as dry wall/brick wall or any other items to simulate the

patient moving about the house. Again tester was encouraged to capture as much detail as possible. At minimum he/she was asked to log the length and width of the room, how close the ICD was to the nearest wall, and whether there were any obstacles between the ICD and the base station.

## Results:

Due to the lack of fixed protocol and variation in home layouts, the test data captured during home testing was not very reliable. However, it still gave a rough estimate how the algorithm behaved due to differences in the room sizes and formation of walls in houses. The average connection rate was greater than 90% in the bedroom and was greater than 85% in living room or other rooms. There were 2 occurrences of false wakeups in the Across Room Test in one home. However, the reason for false wakeups was not clear due to lack of test environment details. The Across Room Test also revealed that the signal attenuation across the walls was dependent upon wall makeup. The connectivity across dry walls and sheet rock walls was acceptable. But the connectivity was drastically reduced across brick walls. Home testing provided confidence that there is low probability of false wakeups due to interference from household electronics.

## *4.3 Clinic Testing*

Four clinical engineers performed Clinic Testing in 7 different hospitals and in 6 different follow-up clinics located in Atlanta, California, Kentucky, and Washington. The testing was performed in waiting rooms, hallways, operating rooms, intensive care units (ICU), telemetry rooms and other settings where there were chances of interference.

For testing the effect of medical equipment present in the operating room, the ICD in a gel box was placed near the implant site outside the sterile field. A typical operating room may include but is not limited to electrocautery systems, fluoroscopy machines, blood pressure

monitors, infusion pumps, echo machines, cardiac ablation equipment, equipment in the ICU lab, ultrasonic doppler flow detectors, EP Monitor systems, etc. During implant, the eMICS algorithm was tested by placing the gel box near each of the medical equipment when it was in use. The algorithm was also tested in the Cardiovascular ICU, Medical ICU, Surgical ICU, and Neuro ICU. The ICD was placed near a location where a patient would be lying with most of the ICU equipment powered on for 15 minutes. The tester was requested to provide a comprehensive list of ICU equipment with test results. Some hospitals have a specialized telemetry floor with remote ECG monitoring systems. The algorithm was tested by placing the ICD close to the remote ECG monitoring systems for approximately 15 minutes. Again the tester was requested to provide a comprehensive list of equipment present in these telemetry rooms with test results. The testers were also requested to test eMICS algorithm by placing the ICD in close proximity to other medical equipment in hospitals such as CT scanners, MRI machines or any medical equipment with the potential of causing false wakeups.

A typical follow-up clinic included Boston Scientific and Medtronic programmers along with St. Jude Medical programmers. The ICD in a gel box was placed in any location where a patient with an implanted device might traverse after arriving at follow up clinic. The test was performed during interrogation and programming at follow-up clinics.

## Results:

The Clinic Testing provided incomplete data due to clinic regulations and restrictions. The hospitals and clinics have restricted access to some of the areas. The test setup before test run and data collection after test run were done by the hospital representative in these areas, and sometimes they forgot to collect data after the test run. Also, not all hospitals and clinics allowed clinical engineers to perform testing in all the desired areas. There was a wide variety of medical equipment on the market, and locations visited during the Clinic Testing did not have all the equipment. For all these reasons, test data captured was also not exhaustive for all medical

equipment present in the different medical facilities. However, the incomplete test results showed that the average connection rate was greater than 75%. The connection was not affected by the people moving about, but might have been affected by bigger medical equipment causing obstruction between the ICD and the base station in operating rooms. There were few instances of false wakeups observed in one of the operating room with very old electrocautery system. It was later found that this old device was also causing interference for almost all other medical equipment in the operating room. The eMICS algorithm was tested at other hospitals with newer electrocautery system without any occurrences of false wakeups.

## *4.4 Field Testing*

Clinical engineers also performed the Field Testing. They tried to test the algorithm at airports and when travelling to and from hospitals or clinics by car. They also tested eMICS algorithm near TV and radio transmission tower. A TV or radio transmission tower could potentially be a very high source of interference, emitting radio frequency signals at television and FM frequencies. If the interference is high enough to generate false wakeups, it can affect the battery life of the implanted device for patients living near the tower. The ICD in a gel box was placed in close proximity to the Sutro tower located in central San Francisco, California during an evening broadcast. The Sutro Tower is shared by ten television stations and four FM radio stations. It also has approximately 184 other small and ancillary antennas for backup and other communication services [14].

## Results:

There were quite a few false wakeups recorded when clinical engineers were travelling to and from the medical facilities. The reason for these false wakeups was unclear as the data was collected at the destination of the travel, and the exact location during the travel when false wakeup occurred could not be determined. There were no false wakeups recorded at the airports

or at the Sutro tower during an evening broadcast. This small incomplete set of Field Testing proved that there is a need for large scale and thorough testing to identify different sources which can cause false wakeup in the ICD.

# 5. Discussion

The eMICS algorithm addressed the drawbacks for both 2.45 GHz band based asynchronized wakeup scheme and 400 MHz band based synchronized wakeup scheme. It was integrated in the Unity device platform without affecting any of the existing algorithm functionality in the ICD. The automated test tool made the repetitive testing easier for engineers as well as provided easy and quick interface to interrogate and program the ICD. Extensive data collection during the initial testing of the algorithm provided enough confidence in the algorithm functionality. The average connection rate between the ICD and base station was greater than 90% up to 15 ft distance and decreased only a little for longer distances. The difference in orientation and height did not affect the average connection rate significantly. The eMICS wakeup efficiency was well above expected and False Wakeup Avoidance algorithm also adjusted the value of *Sniff Threshold* quickly in noisy environments. Therefore, the eMICS algorithm was proposed to be transferred to the PPM phase for unit testing, formal verification and validation testing, and exhaustive environment testing. Initial testing in the TPM phase attempted to cover the environments the ICD was exposed to before and immediately after implant in the clinic as well as the environments the device was exposed to when the patient went home after implant. However, the presence of a wide variety of electrical and electronic equipment in the hospital and the home environment required thorough testing on a larger scale. Also the home environment was not the only environment the patient is exposed to after implant, therefore further testing was required in, but not limited to different industrial work environment, travel vehicles, public places etc.

After more analysis of how algorithm behaves in detailed test runs and in animal studies, the algorithm may be modified and optimized in the PPM phase. One of the proposed alternative algorithms for False Wakeup Avoidance algorithm is to set the value of *Sniff Threshold* to a very high value after the value of *False Wakeup Counter* is equal to the value of *Allowed False*

*Wakeups* and then disable the timer with duration equal to the *Sniff Interval*. This version of algorithm can be helpful if the ICD is suddenly exposed to a noisy environment and encounters false wakeups rapidly. With the currently implemented algorithm, the value of *Sniff Threshold* is incremented by only 1 which might not be enough to avoid more false wakeups. Upon enabling the timer with duration equal to the *Sniff Interval*, the ICD might see more false wakeups and the timer will be disabled again. With the proposed alternate algorithm more false wakeups can be avoided as the value of *Sniff Threshold* is set to vary high value and will converge back to an appropriate value for the environment when ICD is done collecting samples equal to the *Energy Samples* multiplied by 2. The drawback to the alternate version is if the ICD was out of noisy environment before the beginning of the next 2-hour period, it might not be able to see the connection requests from the base station for short duration of time until the value of *Sniff Threshold* converges back. The other proposed enhancement for False Wakeup Avoidance algorithm is to differentiate between the false wakeup when there was no device identification number found and the false wakeup when there was a device identification number found but did not match the ICD's own device identification number. In the follow-up clinic where there are multiple patients with ICD present, it is possible that the ICD sees the device identification number of the other devices.

# 6. Conclusions and Future Work

The TPM version of the eMICS feature was successfully transferred to PPM phase. The initial testing suggested that the algorithm performed above expectation. Lab testing showed that the wakeup reliability was greater than 90% for up to 15 ft distance and was not affected much by change in orientation and height. As the ICD was sniffing every 60-90 seconds, it provided plenty of opportunities to establish a connection, therefore the average connection rate of 90% and above was acceptable. Home testing showed that there are very minimal chances of interference from household electronics. However, the connection rate did get affected by the material used in the walls. Clinic testing showed that the connection rate was acceptable in the operating room and follow-up clinics, and there were very few chances of false wakeups due to other equipment. Field testing showed that there was no risk of false wakeups from TV or radio towers. However, there were some other unknown sources of false wakeups which needs thorough investigation.

Typically an ICD battery reaches end of life in around 6-7 years. However, it does get affected by the frequency of low power and high power electric pulse delivery. The eMICS algorithm with 60-90 second sniff interval will decrease the ICD life by around 0.8% to 1%. It was also proposed to replace the 400 MHz band based synchronized wakeup with the eMICS algorithm to minimize effect on battery life even further. However, it is desired to have *Sniff Interval* of 3-5 seconds. The ZL70101 chip draws around 5mA current during each sniff and performing sniff every 3-5 seconds will have very high impact on the battery life. It will reduce the ICD life by around 16% to 18%. This significant change will increase economical burden on patients as they have to get a replacement ICD more frequently.

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