SHORT RANGE

Use cases and Regulatory Approvals for Wireless Medical Devices

Example use cases and understanding the regulatory challenges of incorporating wireless connectivity into medical devices

White Paper

Author

Pelle Svensson
Product Marketing Manager, Product Center Short Range Radio, u-blox

Abstract

This paper discusses some use cases as well as the challenges related to achieving certifications and approvals for medical devices that contain wireless modules, and how manufacturers of such devices can save efforts when using modules with pass-through certifications.

Contents

Background / Executive summary

With the advent of wireless technology in medical applications, new possibilities open up for medical diagnostic and monitoring equipment in a hospital, health care facility, or for care in the home environment. Medical device manufacturers need to understand the complex regulatory requirements, which cover several interrelated topics, such as radio/wireless compliance, medical device approval, hazard analysis, quality management and overall product safety.

Introduction

Compared to a wired connection, wireless connectivity provides easy mobility for both staff and appliances, in addition to removing the hazards due to tripping on cables such as in a busy emergency (A&E) department. Developers of health care appliances and monitoring equipment have many key design decisions and considerations to make in provisioning wireless communication. Factors such as which wireless protocols to use, regulatory approvals to be gained, and how the design will be powered are all important.

Ever increasingly, patient electrocardiography (ECG) monitoring sensors, blood pressure sensors and infusion pumps transfer data wirelessly to the hospital's servers. This approach not only facilitates intervention-free vital sign monitoring, but also provides validating mechanisms.

Use case possibilities

Before we look into the technical aspects of the wireless solutions, let's look at the following potential use cases:

Connected home health
Connected medication
Connected monitoring
Connected inventory

Connected home health

With the emergence of Internet of Things (IoT) solutions, it is now possible to move patient care into the home in a fashion not previously feasible. For instance, it would be possible to perform medical procedures such as monitoring and follow-up checks in the home. Very simple devices can allow remote caregivers and family to monitor basic activities and can alert them to changes or missed medications. Also, consumer type devices provide for fundamental needs, like monitoring medication and activity. The home hub will connect devices with the Internet so that caregivers can follow activities and provide support with confidence.

Connected medication

With seamless and secure integration of short range wireless technologies, medication can be made more effective in the hospital. See Figure 1, where Wi-Fi is used to transmit infusion pump data to the central system in order to monitor the patient 24/7. Bluetooth is used to wirelessly transmit the data from the barcode scanner to the infusion pump. Wi-Fi will forward the data to the central monitoring system, which verifies that the right fluids and medication are administered to the right patient in the right room. This limits potential human errors and also makes sure the hospital systems are updated effectively and in real-time.

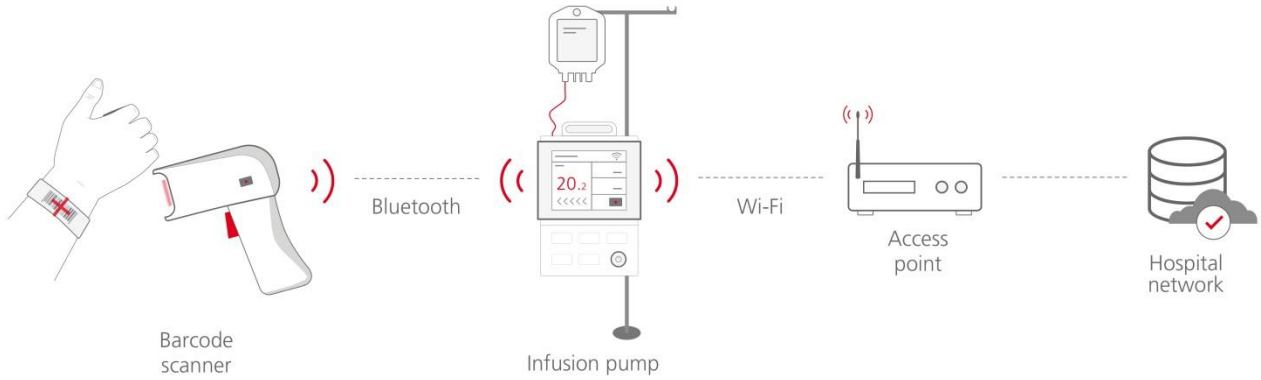

Figure 1: A multiradio gateway module is embedded in the infusion pump making full use of both Bluetooth and Wi-Fi short range radio technologies.

Connected monitoring

Many health authorities now provide defibrillators in shopping malls, airports and other public places. Typically equipped with cellular connectivity, these units benefit from remote monitoring of battery condition and other factors that might affect its ability to operate reliably. The data link also alerts relevant 911/112 operators that the defibrillator has been moved and that somebody is trying to use it.

Connected inventory

Another possible use case is real-time blood bank monitoring (see Figure 2). The environmental conditions under which blood can be stored are very specific and require close monitoring in order to avoid waste and reduced shelf life. The illustrated approach combines a Bluetooth low energy communication gateway and intelligent tags that are attached to each blood bag. Each tag is in fact a Bluetooth low energy module with a temperature sensor and a built-in accelerometer. The module wakes up from sleep-mode and starts advertising its presence to the surroundings when the accelerometer is activated, i.e. when a bag is set in motion. The module then transfers environmental data to the Bluetooth gateway. In this case, Bluetooth low energy was chosen since it is natively supported by smartphones/tablets, offers the lowest power consumption profile and robust, reliable wireless connectivity.

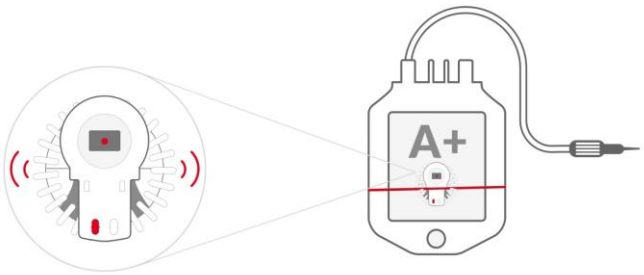

Figure 2: Blood bank monitoring tag created by equipment supplier Tridentify

Compliance with necessary regulations

In the United States, the Food and Drug Administration (FDA or USFDA) must approve all medical devices prior to the seller commencing any marketing or sales activities. In Europe, a CE mark must be obtained as stipulated by the Medical Device Directive (MDD). These are examples of medical device compliance.

In this section, we will cover the necessary basic steps a medical device manufacturer needs to follow in order to bring the product to market. The regulatory landscape is complicated and covers several interrelated topics, such as radio compliance, medical device approval, hazard analysis, quality management, and overall product safety.

Radio type approval

Radio regulatory approval is mandatory for all products with an intentional transmitter. The approval relates to frequency bands, output power, etc. and includes testing to verify compliance with radio spectrum specifications set up by each country.

A wireless module may undergo radio type approval and receive a modular approval in countries where this approach is recognized. In such cases, the radio approval is "passed-through" from the wireless module manufacturer to the end product manufacturer. In the case where the manufacturer opts to make a discrete wireless transceiver design instead of using the module solution, then the approval becomes the product manufacturer's responsibility. The burden of a longer time-to-market and the need for specialist engineering facilities and skilled resources at additional costs is usually sufficiently daunting that most manufacturers will opt for a modular approach rather than for discrete wireless design.

Responsibility for ensuring that radio approval has been achieved in all the countries where the end product is sold or might be used still remains that of the end-product manufacturer. The wireless module manufacturer states the countries and radio regulatory authorities where the part has gained approval. The approval is according to FCC Part 15 specifications in the USA and ETSI R&TTE within the EU.

Pass-through approval acceptance is subject to installing the wireless module as stipulated in the module provider's data sheet. Matching all aspects of module implementation, including antenna placement, power and operating modes is essential.

The FCC recommends that medical device manufacturers regularly verify that their products comply with the latest specifications to remain compliant with current rules, as specifications normally are periodically updated.

Bluetooth / Wi-Fi qualification

Depending on the wireless technology implemented, modules and devices may also require additional testing. For instance, the Bluetooth Special Interest Group (SIG) has implemented the qualification program to ensure interoperability, this program in mandatory.

The Wi-Fi Alliance has an elective program connected to the use of the Wi-Fi logo on Wi-Fi compatible products. For the exact details on both programs, we recommend a visit to the respective organization's web pages

Medical device approval

For FDA approvals, there is no pass-through short cut. Approval must be gained by the manufacturer from the relevant authorities where the end product will be sold and/or used. Many of the evaluation criteria for product approval will vary based on likely use cases. Criteria relating to usability, component failure, electromagnetic interference, user safety (operator and patient) and manufacturing techniques are just some of the conditions and consequences forming part of product approval. Should patient data be transferred, then methods of information privacy and interception will also form part of the approval process.

Electromagnetic compatibility (EMC)

The FDA recommends that medical device manufacturers include electromagnetic compatibility (EMC) requirements in the development, design, testing and performance of a medical device. It is recommended to include EMC testing according to the consensus standard: International Electrotechnical Commission (IEC) EN 60601-1-2. This standard is also applicable to wireless modules and thus ensures that companies providing wireless modules to the medical device industry will undergo testing according to this specification.

Risk Management

As mentioned earlier, the use of multiple wireless technologies in medical devices can benefit patient mobility and the remote monitoring of patients. However, multiple technologies can also be a deployment challenge from a coexistence perspective.

Thus it is increasingly important for medical device manufacturers to consider coexistence with other radio devices, security and EMC in selection of wireless technology.

Analysis of potential areas of risk will include, for example, a variety of consequences should the radio link experience poor performance due to interference, low throughput rates, high latency and denial of service attacks. All aspects of such risks need to be considered in terms of both the event that has caused the condition as well as the measures put in place should such an event occur.

The purpose of the analysis is to predict all possible events that could cause a failure and the steps taken by the device should a certain event be detected.

Hazard and risk analysis are key components of the medical approval process, so engineering management needs to be diligent to ensure it is a core part of the overall product development process.

Risk management activities should also include using risk analysis to identify any potential issues associated with EMC and determining risk acceptability criteria.

Example pre-certified modules

As mentioned above, it is the responsibility of the end medical device manufacturer to gain the needed medical approvals. That being said, there are a number of benefits from embedding a pre-certified module when it comes to approval time/costs, design cycles, testing, time-to-market, etc.

An example of a multiradio module suitable for medical applications is the ODIN-W2 gateway module series from u-blox. Type approved for use in Europe, US, Canada, many Asian countries and other countries, this miniature module features concurrent Wi-Fi (2.4 and 5 GHz) and dual-mode Bluetooth (Classic Bluetooth and Bluetooth low energy) connectivity. This stand-alone gateway module has its own ARM Cortex-M4 microcontroller that runs an embedded Wi-Fi driver and Bluetooth stacks. Connectivity to the end product's application is through a UART or RMII interface (see Figure 3). This approach ensures that the host application does not need to reserve any resources to running wireless stacks. All the radio communications is taken care of by the module, thus off-loading the medical device micro controller.

Certifications, approvals, and environmental features:

- Type Approval
  - FCC (US)
  - IC (Canada)
  - ETSI (EU)
  - MIC (Japan)
  - Korea
  - China
  - Taiwan
  - Brazil
  - Australia/New Zealand
- Bluetooth Qualification
- Medical approval
  - EN 60601-1-2
- Health & Safety
  - EN 62479
  - EN 60950-1
  - IEC 60950-1
- RoHS2
- REACH

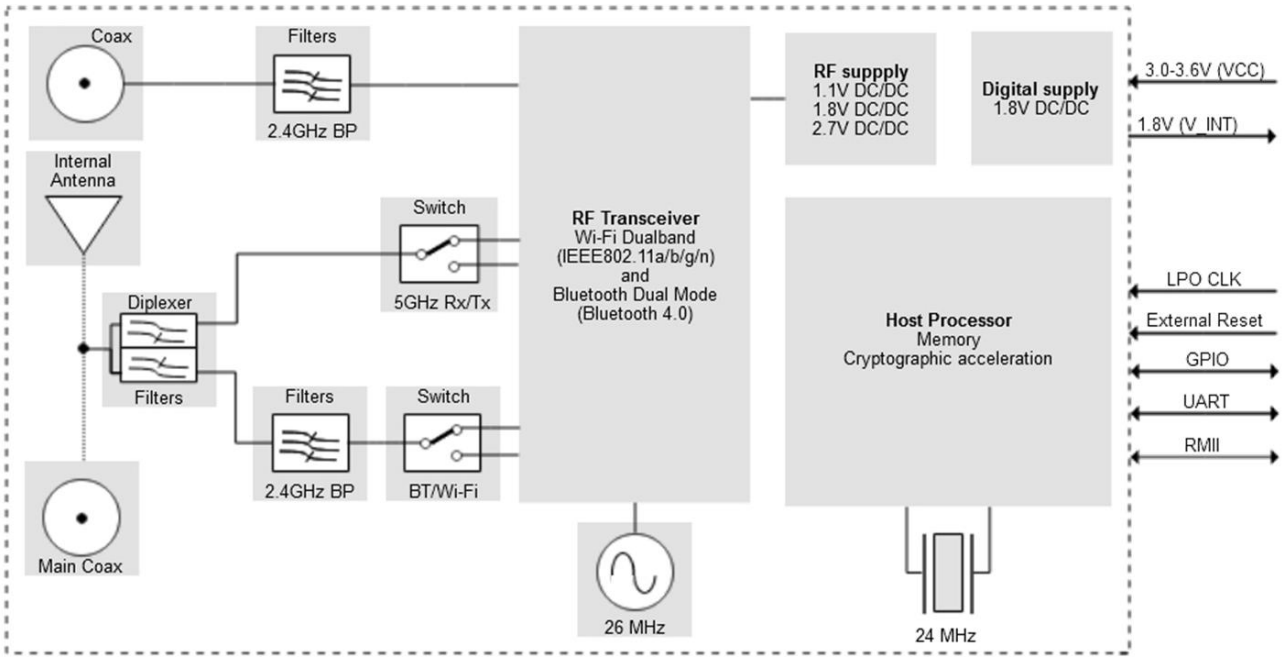

Figure 3: Block diagram of example wireless module – ODIN-W2 from u-blox

When considering which wireless module to select for a medical design, engineers should check that the vendor provides relevant tools to aid rapid design and testing. For example, u-blox provides an evaluation platform for the ODIN-W2 (see Figure 4) together with a PC-based configuration tool called s-center. The s-center evaluation software provides ease of module configuration and evaluation of radio and other performance features.

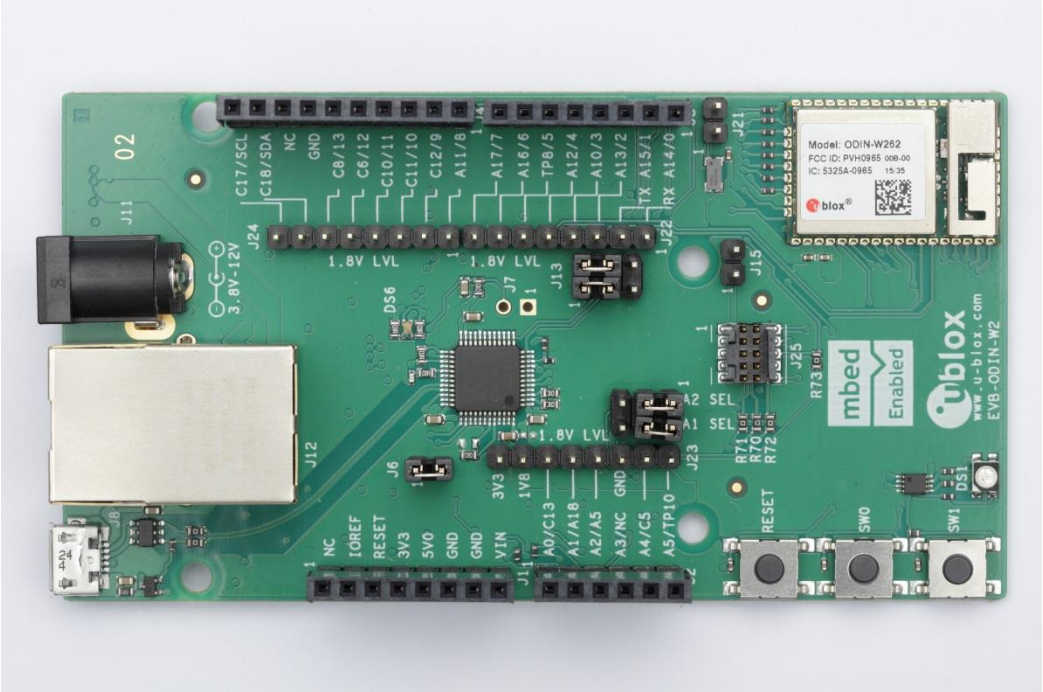

Figure 4: EVK-ODIN-W2 evaluation kit for ODIN-W2

The Bluetooth low energy module NINA-B1 is another example of a module suitable for medical sensor applications or for use in home healthcare devices.

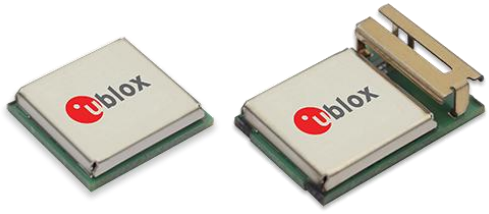

Figure 5: NINA-B1 stand-alone Bluetooth low energy module, with or without internal antenna

This module is based on the latest Bluetooth specification (Bluetooth 4.2) and includes a range of country certifications, thus reducing the effort to gain country specific approvals for marketing of the medical device world-wide. NINA-B1's unprecedented hardware performance and excellent antenna design makes it particularly suitable for demanding medical applications. This compact stand-alone module features Bluetooth low energy v4.2 with Serial port and GATT services pre-flashed on its own ARM Cortex-M4 microcontroller. Particularly suitable in medical sensor solutions, it also offers state of the art power consumption.

About the author

Pelle Svensson is Product Marketing Manager in the Product Center Short Range Radio of u-blox. He joined the Product Marketing team in 2014. Prior to this position, he was Key Account Manager at connectBlue. He holds an MS in Physics, Computer and Control Theory from The Faculty of Engineering (Lund University, Sweden).

About u-blox

Swiss u-blox (SIX:UBXN) is a global leader in positioning and wireless semiconductors and modules for the automotive, industrial and consumer markets. u-blox solutions enable people, vehicles and machines to locate their exact position and communicate wirelessly over cellular and short range networks. With a broad portfolio of chips, modules and software solutions, u-blox is uniquely positioned to empower OEMs to develop innovative solutions for the Internet of Things, quickly and cost-effectively. With headquarters in Thalwil, Switzerland, u-blox is globally present with offices in Europe, Asia and the USA. www.u-blox.com

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[2] www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm

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