WEARABLES AND MEDICAL IOT INTEROPERABILITY AND INTELLIGENCE

CONNECTED WIRELESS MEDICAL DEVICES SECURITY AND SAFETY CONFORMITY ASSESSMENT PROGRAM

INTRODUCTION

With connected devices, telehealth and remote patient monitoring becoming more prevalent, there is an increasing risk to cybersecurity threats. Managing these vulnerabilities can be challenging. Standards along with an industry adopted conformity assessment program may help in managing these risks. It is even more crucial for device manufacturers, clinicians, hospitals and testing organizations to work collaboratively to create a safe and interoperable health care environment.

IEEE P2621 Standard

Medical devices used for monitoring and managing diabetes provide life-saving benefits to patients and effective implementation options to healthcare providers. These devices include blood and continuous glucose monitors, insulin pumps, pens and other insulin delivery devices, and closed loop artificial pancreas systems and others. With ever-increasing connectivity and data exchange between these diabetes devices, other devices (such as smartphones), and the Internet, there is an increased risk to the safety and privacy of the patient and to the integrity of the healthcare provider. This standard, therefore, is needed to aid medical manufacturers in the development of more secure, and therefore safer, products as well as to provide the framework for enhancing assurance across the relevant stakeholder community.

IEEE Connected Wireless Health Device Security Certification Committee

IEEE intends to issue a call for Participation for entities to join this committee. Some of the main goals of this committee would be to ensure:

- All healthcare devices used by end-users (consumers) should conform with IEEE 2721 and other future standards related to medical devices
- Device conformity should be certified by an independent body
- Testing and certification processes adhere to the certification scheme developed by the committee
- Testing should be performed by IEEE recognized test laboratories that are competent in testing to the relevant standards

Who should participate

- Device Manufacturers, Integrators, software developers
- Test laboratories
- Academia
- End-user community (Healthcare Facilitators, Healthcare Device advocates, Hospitals, etc.)
- Government Regulators

GET INVOLVED:

We are currently recruiting advisors and participants for the program. Please contact Maria Palombini, m.palombini@ieee.org for more details.