

An Informative Whitepaper

**Electrical Isolation
and
Improved Electromagnetic
Compatibility
for
Personal Healthcare Devices
using
Universal Serial Bus**

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Scope of This Release

This version of the informative Whitepaper incorporates comments from the working group for redistribution and review.

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1 Introduction

1.1 Audience

The audience of this white paper is the classic USB consumer product manufacturers, who are new to the healthcare device environment.

This document is provided for informational reference only, and the authors make no guarantees about the accuracy or completeness of the content. In addition, the complete standards that are referenced should be read and reviewed by all healthcare device manufacturers as standard practice.

Please note that this whitepaper **should not** be considered as a replacement to reading the complete standards, but serve as a guide to the more critical portions of the standards.

1.2 Overview

This whitepaper is intended as an introduction to the IEC standards that may need to be followed in certain types of USB devices, including some that use the Personal Healthcare Device Class specification.

1.3 Scope

This whitepaper points to industry standards that address electrical isolation and electromagnetic compatibility for medical electrical equipment and its usage. Some of these standards may apply to certain types of personal healthcare devices. These are industry standards containing full test methodology and conditions that help ensure full product function and safety.

The intent is to highlight critical areas and is not a replacement for reading, reviewing and implementing the full scope of the reference standards listed below.

1.4 Reference Standards Documents (Partial List)

Universal Serial Bus Specification, Revision 2.0, April 27, 2000, <http://www.usb.org>
Universal Serial Bus Device Class Definition for Personal Healthcare Devices (under ballot)
IEC/UL 60601-1-2005 Medical electrical equipment – part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Medical electrical equipment – part 1-2: Electromagnetic compatibility – Requirements and tests
IEC 61000-4-2: Electromagnetic compatibility – part 4-2: Testing and measurement techniques- Electrostatic discharge immunity test
IEC 61000-4-4: Electromagnetic compatibility – part 4-4: Electrical fast transient/burst immunity test
IEC 61000-4-5: Electromagnetic compatibility – part 4-5: Testing and measurement techniques – Surge immunity test
IEC 61000-4-8: Electromagnetic compatibility – part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test
IEC 61000-4-11: Electromagnetic compatibility – part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests

1.5 Terms and Abbreviations

Electrical isolation	
ESD	Electrostatic discharge
IEC	International Electrotechnical Commission
EMC	Electromagnetic Compatibility

Immunity	Immunity means the ability of apparatus to perform satisfactorily against the performance criteria specified for the device in the presence of an electromagnetic disturbance.
Susceptibility	Susceptibility is a lack of immunity against internal or external interference.

Please see Universal Serial Bus Device Class Definition for Personal Healthcare Devices specification v1.0 for a list of additional terms and abbreviations.

2 PHDC Topology

Figure 1 - PHDC Topology shows the example topology of personal healthcare devices and USB hosts. It shows the personal healthcare devices function in the overall model. This paper addresses the "Wired USB" portion of the diagram. This whitepaper is of most use for personal healthcare devices that perform a medical function.

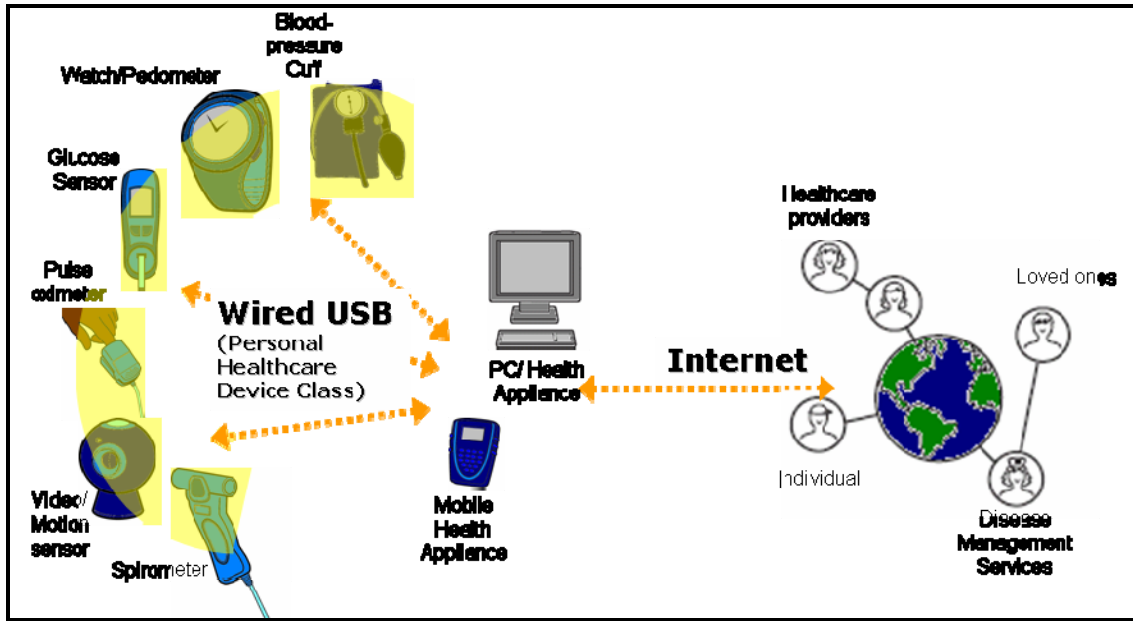


Figure 1 - PHDC Topology

3 Personal Healthcare Devices

The PHDC focuses on the interactions between USB personal healthcare devices and USB hosts. Examples of the types of devices that are expected to send data via the PHDC are listed in [Table 1 - Example PHDC Devices](#). Not all of these devices perform medical functions; however, for those that may, this whitepaper may be useful.

Table 1 - Example PHDC Devices

Theme	Example PHDC Devices
Health and Wellness	Fitness equipment, including: pedometers, sports watches, treadmills, and exercise bikes.
Disease Management	Disease management equipment, including: blood pressure monitors, glucose meters, weight scales, pulse oximeters, pulse meters, and thermometers.
Aging Independently	Monitoring equipment, including: motion sensors and pill reminders.

4 Electrical Isolation

IEC 60601-1 defines medical equipment electrical safety conditions to protect patients, caregivers, and surroundings. The areas to highlight are covered under “patient leakage” found in clause 8.7.4.7 (a, b, c, d, h) and “patient auxiliary current” found in clause 8.7.4.8. Please refer to IEC 60601-1 for complete test parameters and conditions.

5 EMC

Medical equipment and medical systems must have adequate immunity to be able to provide basic safety and essential performance in the presence of electromagnetic disturbances. This applies to both conditions of emissions and immunity. Since November 2005, medical equipment has had to comply with the updated IEC 60601-1-2-2005 EMC standard.

6 ESD

IEC 61000 contains certain immunity tests and calls out important testing conditions that deserve to be highlighted.

IEC 61000-4-2 is an ESD test. It is highly recommend that all of the pins (contacts) of all ports of the unit under test be tested to ensure critical protection and isolation. These test conditions are different than what is called out in IEC 61000-4-2 and are very important to note.

IEC 61000 contains clauses 4-5 Electrical Fast Transient/Burst, 4-5 Surge, 4-8 Power frequency (50/60 Hz) magnetic field and 4-11 Voltage dips, short interruptions, and voltage variations on power-supply-input line. These tests should be conducted as described in the IEC 61000 standard.

7 Summary

Please note that this whitepaper should not be considered as a replacement to reading the complete standards, but serve as a guide to the more critical portions of the standards and some unique conditions as they apply to USB products.

The end result of performing these recommended electrical isolation, EMC and ESD tests will offer the consumer a safer and more robust USB device.