IPC-6013EM

Medical Applications Addendum to IPC-6013E

Qualification and Performance Specification for Flexible/Rigid-Flexible Printed Boards

Developed by the IPC-6012 Medical Addendum Task Group (D-33AM) of the Rigid Printed Board Committee (D-30) of IPC

Users of this publication are encouraged to participate in the development of future revisions.

Contact:

IPC

Tel 847 615.7100
Fax 847 615.7105

Table of Contents

Figures

Tables

Medical Applications Addendum to IPC-6013E
Qualification and Performance Specification for Flexible/Rigid-Flexible Printed Boards

0.1 Scope This addendum covers qualification and performance requirements of Flexible/Rigid-Flexible Printed Board for Medical Device Applications. The printed boards may have a design that contains HDI and Design Level D density with special requirements to production, test and qualification.

This addendum provides requirements to be used in addition to, and in some cases, in place of, those published in IPC-6013E to ensure the reliability of printed boards that must meet requirements to High Reliability Medical Applications described as IPC Class 3 under section 0.1.5 of this addendum.

0.1.1 Purpose The purpose of this addendum is to provide requirements for qualification and performance of Printed Boards for High Reliability Medical Device Applications. The requirements written in this document support regulatory guidance provided by the FDA and Medical Device Directives.

0.1.2 Precedence The procurement documentation takes precedence over this addendum and referenced standards. In the event of a conflict between this addendum and the applicable documents cited herein, this addendum takes precedence. Where referenced criteria of this addendum differ from the published IPC-6013E, this addendum takes precedence.

0.1.3 Existing or Previously Approved Designs This addendum **shall not** constitute the sole cause for the redesign of previously approved designs. When drawings for existing or previously approved designs undergo revision, they should be reviewed and changes made that allow for compliance with the requirements of this addendum.

0.1.4 Use of this Addendum This addendum **shall not** be used as a stand-alone document.

Where criteria are not supplemented, the Class 3 requirements of IPC-6013E **shall** apply. The clauses modified by this addendum do not include subordinate clauses unless specifically stated (i.e., changes made to 3.5 do not affect 3.5.1 unless 3.5.1 is also addressed in this addendum). Procurement documentation **shall** specify when requirements to design level D is applicable.

0.1.5 IPC Classification For Medical Applications To evaluate best suitable IPC classification, medical device manufacturers and users should consider the risk hazard analysis and human factors evaluation of the device, as recommended by ISO 14971. This document does not define Medical Device Classifications, it defines printed circuit board acceptability classifications described as IPC Class 1, 2 and 3. Table A-1 provides guidance on the IPC Class level depending on the medical device application, technology complexity and printed circuit board acceptability requirements.

Table A-1 Medical Performance Classes

IPC Performance Class	Application	Description
Class 1	Low Risk Medical Electronics	Includes limited use products suitable for applications where the requirement is function of the completed product and the risk of injury to the patient, equipment operator, or environment is nonexistent.
Class 2	As Low As Reasonably Practicable (ALARP) Medical Electronics	Includes products where continued performance and extended life are required, and uninterrupted service is preferred, but interrupted service will have low risk of injury to the patient. The risk level **shall** be defined in risk hazard analysis of the medical device.
Class 3	High Risk Medical Electronics	Includes equipment and implantable devices where continued high performance or performance-on-demand is critical; handling/storage and operating environments may be harmful to the device, and product failure can result in high risk of injury to the patient. The risk level **shall** be defined in risk hazard analysis of the medical device.

For a risk to be ALARP, it must be possible to demonstrate that the cost involved in reducing the risk further would be grossly disproportionate to the benefit gained.

0.1.6 Design Producibility Levels This addendum shows requirements for 3 design levels: HDI design level D, HDI design level C and Standard Design level A-B as described in Tables A-2 and A-3. The addendum specifies requirements to printed board performance and acceptability for each design level to reach a satisfactory reliability for High Risk Medical Device Applications.

Table A-2 Design Producibility Levels*

Level A General Design Producibility - Preferred
Level B Moderate Design Producibility - Standard
Level C Least Design Producibility - Reduced
Level D Advanced Design Producibility - Exceedingly Reduced

* Level A, B and C are currently described in IPC-2220 series. Design Level D is a description of designs exceeding current levels in IPC-2220 series for Printed Board Design. This document will be updated when IPC-2220 series covers Design Level D parameters.

Table A-3 Description of Design Producibility Levels

Product Complexity and Density Level	HDI Design Level D	HDI Design Level C	Standard Design Level A-B
Thickness	<0.5 mm	Any	Any
Track/Gap	<60 µm	60-99 µm	>100 µm
Holes	<100 µm	<150 µm	>150 µm
Printed Board Technology	FPC, Rigid-Flex, Rigid	FPC, Rigid-Flex, Rigid	FPC, Rigid-Flex, Rigid
Application	Pacemaker, Hearing Aid etc.	Other Implants and High End Applications	Standard/Simple Applications

0.1.7 Traceability Traceability marking, traceability to process and material data **shall** be in accordance with IPC-1782A level 4.

Individual printed boards **shall** include a unique identifier for traceability to a lot, panel, and location within the manufacturing panel so as to provide traceability to process and process equipment. The unique identifier can be Alphanumeric, 2D Barcode, or equivalent.

0.1.8 Compliance

0.1.8.1 Compliance to Product Specification and Requirements To secure compliance to product performance in the Medical Device Application, a computer readable Digital Specification **shall** be created during the product development process. The Digital Specification **shall** specify the product requirements in all printed board procurement stages between buyer and seller through the complete product lifecycle.

The Digital Specification **shall** as a minimum encompass the parameters as written in this Medical Addendum and IPC-6013E.

The Digital Specification **shall** be used in Request for Quotations to protect the buyer and secure that the seller has sufficient capability to meet the Specified Qualification and Performance Requirements.

The supplier **shall** confirm transparency and traceability of materials, production sites and production processes used in his quotation.

A bill of material including base material brand and type, solder mask brand and type and solderable finish, **shall** be specified in the quotation.

If one of the parties are unable to import to his system a computer readable digital specification an electronic paper **shall** be AABUS.

0.1.8.2 Regulatory Compliance The regulatory compliance requirements of the country the medical device is being employed in **shall** take precedence over the requirements in this addendum. If to achieve Regulatory Compliance this IPC standard addendum has to be deviated from, it **shall** be reported to the customer.

0.1.8.2.1 United States FDA Mission Statement The Food and Drug Administration of the United States is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.