Specification IEC 60601-1-2:2014 Edition 4 requires specific supporting documentation to be provided by the manufacturer at the time of test and also documentation required to be provided with the product to the end user. This document outlines the documentation that will be required by Element prior to the EMC test programme.

The ‘Accompanying Documents’ section of the standard - Clause 5.2 of IEC 60601-1-2:2014 Edition 4 specifies documentation that the manufacturer will be required to supply to the end user in terms of information on the product and a manufacturers declaration. This consists of a number of warning statements that the manufacturer has to provide to the end user.

This document sets out the requirement for the manufacturer to define the essential performance of the equipment under test and the basic safety functions relating to that essential performance. This will ensure that during testing all relevant equipment parameters will be checked in line with the defined essential performance.

Essential performance (of an equipment or system) in this case is: The performance characteristics necessary to maintain the residual risk within acceptable limits.

Element are not medical experts and as such cannot determine the essential performance of medical equipment. The specification requires the manufacturer of the equipment to do this. The specification states:

“Before IMMUNITY testing begins, the MANUFACTURER shall determine specific, detailed IMMUNITY pass/fail criteria, based on applicable part two standards or RISK MANAGEMENT, for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES. The MANUFACTURER shall also determine how the ME EQUIPMENT or ME SYSTEM will be monitored during the tests to check for compliance with the specific pass/fail criteria. These pass/fail criteria and this monitoring specification should be included in the test plan and shall be included in the test report and the RISK MANAGEMENT FILE.”

In defining the essential performance it should be noted that if complicated and lengthy monitoring methods are required to be employed during the test programme then the required test time could increase. This will potentially have cost implications and Element will inform the client/client contact prior to the commencement of testing.

**The manufacturer should provide the following information prior to the time of testing:**

**[1] Essential Performance**

All medical equipment must undergo a risk analysis assessment to ISO 14971:2012 with guidance from annex F of IEC 60601-1-2:2014 Edition 4. IEC 60601-1-4:2014 Edition 4 requires that the risk analysis is carried out in conjunction with an EMC expert, Element can provide this expertise through our consultancy department should it be required. Completion of the risk analysis will enable the essential performance and all the key parameters that need to be monitored during testing to be defined. Reference should also be made to the EN60601-2-X (Part 2) standard appropriate to the individual Equipment Under Test. There are many part 2 standards and a basic list can be found in the appendix of this document.

The risk assessment should identify the elements of the equipment that are key to its performance and identify how if affected by immunity phenomena this could impact on the safety of the equipment.

For each aspect of essential performance a definition of pass fail criteria should be provided. This may be for example, a tolerance, a change in mode, noise on a measurement parameter etc. IEC 60601-1-2:2014 Edition 4 Annex I covers selection of pass/fail criteria in detail and reference should be made to this prior to deciding on the criteria.

**[2] Immunity to RF Wireless Communications Equipment**

IEC 60601-1-2:2014 Edition 4 section 8.10 covers test requirements for evaluation of wireless transmitters used in the vicinity of the EUT. Table 9 in this section covers the most common RF frequency bands where transmitters could be expected to operate used in the vicinity of the equipment under test. This is not an exhaustive list and reference should be made to the table and guidance sought on any additional transmitters that could be expected to be used in the vicinity of the equipment under test not covered by the table. This exercise should be part of the risk analysis generation and documented as such.

**[2] Test Plan**

Prior to any testing IEC 60601-1-2:2014 Edition 4 requires a test plan to be produced in line with IEC 60601-1-2:2014 Edition 4 Annex G. Element can aid in the production of a test plan through our consultancy department if required.

**[3] Supporting EUT Documentation**

The key information that Element need from the manufacturer prior to the test is:

* The definition of essential performance and the basic safety functions
* The monitoring methods used to decide if the essential performance has been met with any degradation occurring not effecting the basic safety functions (i.e. is the monitoring method chosen adequate to ensure that the basic safety of the equipment is met during the testing)
* The pass/fail criteria of the EUT
* Documentation stating additional frequencies that should be tested as per section 8.10 of IEC 60601-1-2:2014 Edition 4.
* Test Plan

Element Form RF104 (EUT Declaration) should be used to record the essential performance, equipment operating modes and pass/fail criteria.

For Medical equipment, signing the RF104 Form attests to the fact that a risk analysis has been carried out and the essential performance has been declared by the manufacturer.

For monitoring of essential performance parameters the manufacturer may be required to attend the testing and provide assistance as deemed necessary, depending upon the complexity of the equipment and any potential risk of under performance to tolerance.

**Contact Information:**

Should you need assistance with the content of this form or completing form RF104 then please use one of the following contact points:

Peter Green

TEL: 01695 556666

Peter.green@element.com

Stewart Barrowclough

TEL:01695 556666

Stewart.barrowclough@element.com

Steve Hayes (Risk Analysis Consultancy)

TEL:01684 571700

Steve.hayes@element.com

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I have read and understood this document and confirm that I have provided the essential performance, monitoring methods and pass/fail criteria requirements to Element and that these have been made in conjunction with both the manufacturer and an EMC expert following guidance in IEC 60601-1-2:2014 Edition 4 annex F and I:

|  |  |
| --- | --- |
| **Signature:** | **Name:** |
| **Position:** | **Date:** |

**ANNEX**

**EN60601-1-2 standards**

**this is not an exhaustive list but gives the most common and up to date versions as of the date of publication of this document, for an up to date list please make reference to the medical Official Journal. For compliance outside of Europe later IEC versions of these standards may exist and should be considered.**

**The latest Medical Official Journal can be found here:**

[**http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices/index\_en.htm**](http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices/index_en.htm)

EN 60601-2-1:1998 + A1:2002 Medical electrical equipment — Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV IEC 60601-2-1:1998

EN 60601-2-2:2009 Medical electrical equipment — Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories IEC 60601-2-2:2009

EN 60601-2-3:1993 +A1:1998 Medical electrical equipment — Part 2: Particular requirements for the safety of short-wave therapy equipment IEC 60601-2-3:1991

EN 60601-2-4:2003 Medical electrical equipment — Part 2-4: Particular requirements for the safety of cardiac defibrillators IEC 60601-2-4:2002

EN 60601-2-5:2000 Medical electrical equipment — Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment IEC 60601-2-5:2000

EN 60601-2-8:1997 + A1:1997 Medical electrical equipment — Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV IEC 60601-2-8:1987

EN 60601-2-10:2000 + A1:2001 Medical electrical equipment — Part 2-10: Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10:1987

EN 60601-2-11:1997 + A1:2004 Medical electrical equipment — Part 2-11: Particular requirements for the safety of gamma beam therapy equipment IEC 60601-2-11:1997

EN 60601-2-12:2006 Medical electrical equipment — Part 2-12: Particular requirements for the safety of lung ventilators — Critical care ventilators IEC 60601-2-12:2001

EN 60601-2-13:2006 + A1:2007 Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems IEC 60601-2-13:2003

EN 60601-2-16:1998 + AC 1999 Medical electrical equipment — Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:1998

EN 60601-2-17:2004 Medical electrical equipment — Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004

EN 60601-2-18:1996 + A1:2000 Medical electrical equipment — Part 2: Particular requirements for the safety of endoscopic equipment IEC 60601-2-18:1996

EN 60601-2-19:2009 Medical electrical equipment — Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators IEC 60601 IEC 60601-2-19:2009

EN 60601-2-20:2009 Medical electrical equipment — Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601 IEC 60601-2-20:2009

EN 60601-2-21:2009 Medical electrical equipment — Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009

EN 60601-2-22:1996 Medical electrical equipment — Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment IEC 60601-2-22:1995

EN 60601-2-23:2000 Medical electrical equipment — Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment IEC 60601-2-23:1999

EN 60601-2-24:1998 Medical electrical equipment — Part 2-24: Particular requirements for the safety of infusion pumps and controllers IEC 60601-2-24:1998

EN 60601-2-25:1995 + A1:1999 Medical electrical equipment — Part 2-25: Particular requirements for the safety of electrocardiographs IEC 60601-2-25:1993

EN 60601-2-26:2003 Medical electrical equipment — Part 2-26: Particular requirements for the safety of electroencephalographs IEC 60601-2-26:2002

EN 60601-2-27:2006 Medical electrical equipment — Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment IEC 60601-2-27:2005

EN 60601-2-28:2010 Medical electrical equipment — Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010

EN 60601-2-29:2008 Medical electrical equipment — Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008

EN 60601-2-34:2000 Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment IEC 60601-2-34:2000

EN 60601-2-36:1997 Medical electrical equipment — Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy IEC 60601-2-36:1997

EN 60601-2-37:2008 Medical electrical equipment — Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2007

EN 60601-2-39:2008 Medical electrical equipment — Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2007

EN 60601-2-40:1998 Medical electrical equipment — Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment IEC 60601-2-40:1998

EN 60601-2-41:2009 Medical electrical equipment — Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis IEC 60601-2-41:2009

EN 60601-2-43:2010 Medical electrical equipment — Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2010

EN 60601-2-44:2009 Medical electrical equipment — Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2009

EN 60601-2-45:2001 Medical electrical equipment — Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2001

EN 60601-2-46:1998 Medical electrical equipment — Part 2-46: Particular requirements for the safety of operating tables IEC 60601-2-46:1998

EN 60601-2-47:2001 Medical electrical equipment — Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems IEC 60601-2-47:2001

EN 60601-2-49:2001 Medical electrical equipment — Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment IEC 60601-2-49:2001

EN 60601-2-50:2009 Medical electrical equipment — Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment IEC 60601-2-50:2009

EN 60601-2-51:2003 Medical electrical equipment — Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs IEC 60601-2-51:2003

EN 60601-2-52:2010 Medical electrical equipment — Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009)

EN 60601-2-54:2009 Medical electrical equipment — Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009