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15 Steps to get approval to IEC 60601-1 (Editions 3.0 & 3.1)

Standard on Medical Electrical Equipment & Systems (MEE&S)

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Presented by: **Leo Eisner – The "IEC 60601-1 Guy"**

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Today's Agenda

IEC 60601-1 Basics	**10 min.**
15 Steps to Approval	**55 min.**
Resources	**5 min.**
Questions	**15 min.**

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About the Presenter

Leo Eisner (PE) is the President and Principal Consultant of Eisner Safety Consultants; a consulting group focused on helping medical device companies through the product safety, EMC, international regulatory and quality system processes. Our team of experts helps you get your products to market in a timely manner.

Leo is a registered Professional Engineer (P.E.) in the Safety Engineering discipline. Leo has worked at some of the leading Safety Agencies in the world (UL & TÜV Product Service) & has 30 years experience in the Product Safety arena. He worked for Karl Storz Imaging as a Compliance Engineer prior to starting his own consulting firm 19 years ago. Leo has been a notified body auditor for TÜV Product Service & NSAI. He was authorized to audit to the EU MDD, CMDR, ISO 13485, & was a technical reviewer for electro-medical devices for NSAI.

Leo is a co-chair of the U.S. TAG (technical advisory group) for IEC/SC 62D, a member of the US TAG for TC 62 (Electrical Equipment in Medical Practice), SC 62A (Common Aspects of Electrical Equipment Used in Medical Practice) & SC 62D (Electromedical equipment). Leo is on the AAMI Electrical Safety (ES) Committee, which develops the US version of the IEC 60601-1 standard (ANSI/AAMI ES 60601-1). He is the convener of SC62D JWG9 "Lens removal and vitrectomy devices for ophthalmic surgery". Leo is a member of the TC 62/SC 62A/WG 14 (Testing to General Safety Standard – The Working Group is chartered to develop recommendations regarding interpretation & application of IEC 60601-1 to testing of medical electrical equipment, and to deal with general testing requirements.)

To support the increase in demand for Home Use medical devices & Wearables Leo's a member of the AAMI committee for Home Use Medical Devices/Emergency Medical Devices Services (& the respective IEC SC62A/JWG's 6 & 8) & of the US TAG for Active Assisted Living SyC (System Committee approach for an aging population, their families and care provides with solutions that enable them to live longer but also to live a better life at home instead in a hospital or nursing home or other clinical setting – this SyC includes the home care medical device industry).

IEC 60601-1 Basics

The IEC 60601 Series too

IEC 60601-1, 2nd & 3rd ed., & ed. 3.1

IEC 601-1, 2nd ed. + A1 + A2

INTERNATIONAL STANDARD

601–1

1988

AMENDMENT 1
1991–11

AMENDMENT 2
1995–03

Medical electrical equipment

Part 1:
General requirements for safety

Note: This document was prepared by the Secretariat of IEC/SC 62A to facilitate the development of the third edition of IEC 601–1. Any other use of this document is prohibited.

Bureau Central de la Commission Electrotechnique Internationale 3, rue de Varembé Genève, Suisse

IEC 60601-1, 3rd ed.

INTERNATIONAL STANDARD

IEC 60601-1

Third edition
2005-12

Medical electrical equipment –

Part 1:
General requirements for basic safety and essential performance

International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

IEC 60601-1, 3rd ed.+ A1 (ed. 3.1)

IEC 60601-1

Edition 3.1 2012-08

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

IEC 60601-1:2005+A1:2012(E)

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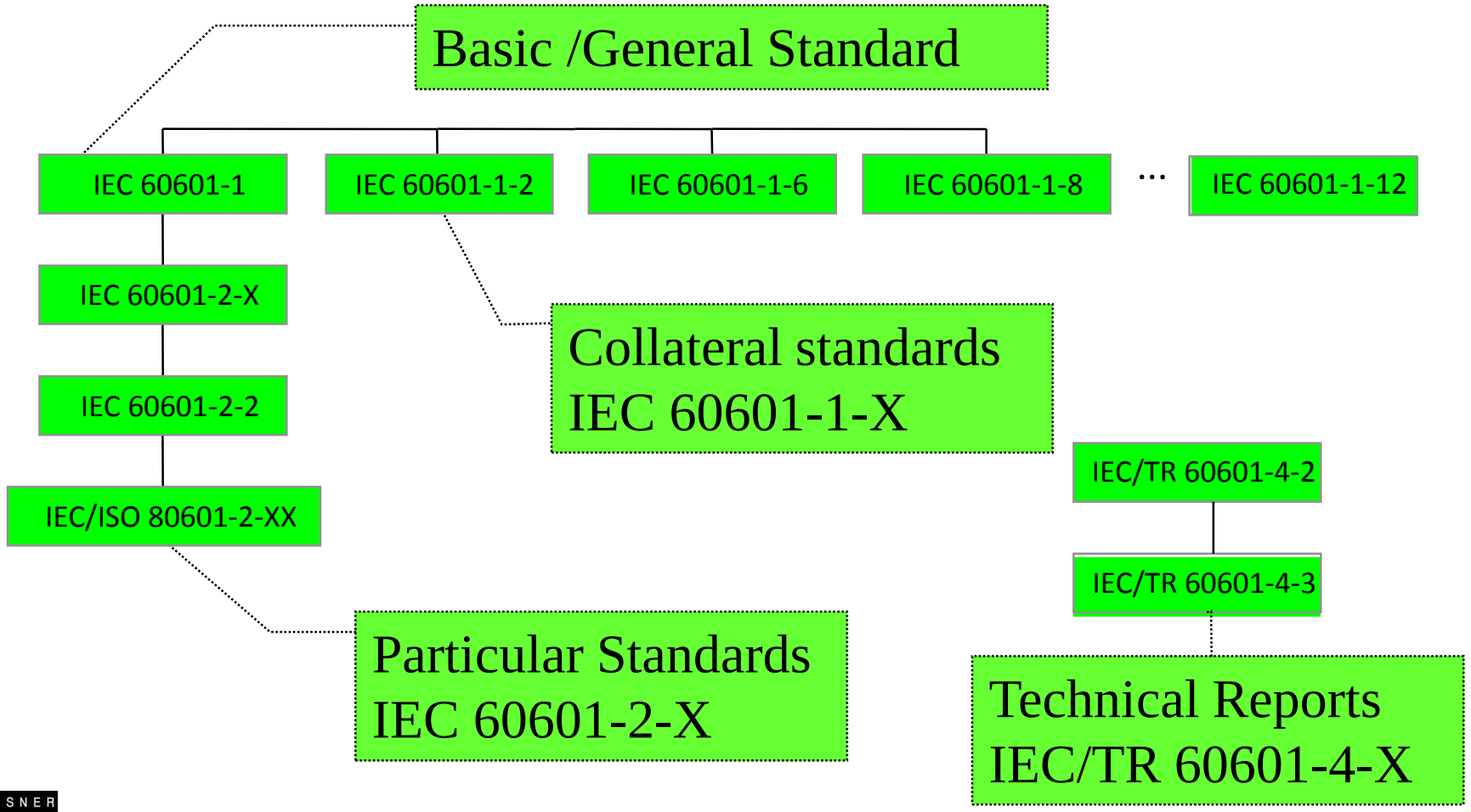
60601 Series of Standards & Technical Reports



Structure of 60601 Series – those dashes matter …

- 60601-1 – General standard
  - **Applies to all** electrical medical devices
- 60601-1-X – Collateral standards
  - **Determine if applies to your** medical devices
  - List of Current/Withdrawn Collaterals – Appendix
- 60601-2-X – Particular standards
  - **May apply to your device** technology(ies)
- 60601-3-X – **Withdrawn**

Structure of 60601 Series – those dashes matter …

- 60601-4-X – Technical Reports (**Guidance & Interpretation**)
  - IEC TR60601-4-2:16
    - Electromagnetic immunity: performance of MEE&S
  - IEC TR60601-4-3:15
    - Unaddressed safety aspects 60601-1, 3rd ed. & proposed new requirements
  - **Draft** IEC TR60601-4-1
    - MEE&S employing a degree of autonomy (Medical Robots)
  - **Draft** IEC TR60601-4-4
    - Writers of -2-XX Stds - Creating alarm system-related requirements

History of 60601-1 & Planned Changes

- IEC 601-1:1977, 1st ed.
- IEC 60601-1:1988, 2nd ed. + A1:1991 + A2:1995
- IEC 60601-1:2005, 3rd ed. + A1:2012
- **Draft** IEC 60601-1, 3rd ed. + A2 **planned for 2019**
- **Start ≈ 2019** IEC 60601-1, 4th ed. **planned for 2024**

What Version of IEC 60601-1 are Countries Accepting

- IEC 60601-1:1988, 2nd ed. + A1:1991 + A2:1995
  - NRTL (US) UL 60601-1 – US Safety Certification Mark Only – No current transition date (Not aligned with FDA)
  - China as GB 9706.1-2007 (Drafting ed. 3.1 ≈ 2016 will be mandatory)
  - Japan til May 31, 2017 - Japanese version
- IEC 60601-1:2005, 3rd ed.
  - Canada (Health Canada) either CAN/CSA C22.2 no. 60601-1-08:2008 or IEC 60601-1:2005, 3rd ed. + Cor. 1:2006 + Cor. 2:2007 (neither has a set transition date to ed. 3.1)
  - EU (MDD) EN 60601-1:2006 + AC:2010 til Dec 31, '17 (No grandfathering forward for existing & new device)
  - Japan til Feb 28, 2019 - Japanese version

What Version of IEC 60601-1 are Countries Accepting

- IEC 60601-1:2005, 3rd ed. + A1:2012
  - FDA (US) as of Aug 2, '16 AAMI/ANSI ES60601-1:2005(R)2012 + A1:2012 + C1:2009 + A2:2010 (All Reaffirmed 2012 other thaN A1) Consolidated text
    - all new & existing device submissions Recognized Consensus Standard
  - NRTL (US) AAMI ES60601-1:2005/(R)2012 (Same as above standard) – US Safety Certification Mark
  - Canada (Health Canada) either CAN/CSA C22.2 No. 60601-1-14:2014 or IEC 60601-1:2012, ed. 3.1
  - Canada (Standards Council of Canada) CAN/CSA C22.2 No. 60601-1-14:2014 – Canadian Safety Certification Mark
  - EU (MDD) EN 60601-1:2006 + A1:2013 after Jan 1, '18 (No grandfathering)
  - Japan starting March 1, 2019 mandatory - Japanese version

What Version of IEC 60601-1 are Countries Accepting

- Particular Standards Cause Confusion – Check with the specific regulator
  - EU and Canada have transition policies in place to deal with some -2-XX standards based on 2nd ed. of 60601-1 as not all up to 3rd ed. yet.

15 Steps to Approval

For a successful project

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Step 1

Project Plan for 60601-1 Approval

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Step 1 – Project Plan for 60601-1 Approval

- Applicable steps of this process should be included in the Project Plan
  - Could be a separate sub-section of overall Project Plan
- Each Project is different – yours may have additional or fewer tasks
- Use Project Planning software to manage the details

Step 2

Determine which standards
apply to your device

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Step 2 – Determine Applicable Standards for Your Device

- Always check Scope of the Standards & DEFINED TERMS in Scope
  - IEC 60601-1, ed. 3.1 – * Scope (1.1*) – Applies to BASIC SAFETY & ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT (3.63*) & ME SYSTEMS (3.64*)
  - Most medical electrical devices fall under 60601 series other than (1.1*):
    - IVD equipment outside of MEE definition (IEC 61010 series)
    - Active implantables or implantable parts (ISO 14708 series)
    - Medical gas pipeline systems (ISO 7396-1)
      - Note: ISO 7396-1 applies rqrts of 60601-1-8 to certain monitoring & alarm systems
  - If not in scope, likely in wrong standard, <u>but</u> regulators may push you to use out of scope standard

Step 2 – Determine Applicable Standards for Your Device

- Which Collateral Standards apply?
  - If 60601-1, ed. 3.1 being used than bold items at a min. apply
    - **60601-1-2**, -1-3, **-1-6**, -1-8, -1-9 (Brazil 12/1/16), -1-10, -1-11, -1-12
    - OD-2055 IECEE CB Scheme – Helpful tool for Collaterals selection (Appendix – 3 slides)
- Any Particular/Other Standards apply?
  - Could have multiple Particular Standards
  - 1st search titles on IEC & ISO sites for 60601-2-XX & 80601-2-XX standards
  - May be other standards that apply as well – search by technology /other
  - Then review the scopes of titles that you think apply

Step 3

Classify your product per IEC 60601-1
& any Collateral & Particular Standards

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Step 3 – Classification (Cl. 6)

- Protection against electric shock classifications (6.2 *)
  - Power source
    - External power source either CLASS I or CLASS II
    - Other MEE - INTERNALLY POWERED MEE
  - APPLIED PARTS
    - TYPE B  BF  or CF  APPLIED PARTS
    - APPLIED PARTS may additionally be DEFIBRILLATION-PROOF APPLIED PARTS 
- Protection against harmful ingress of H_2O or particulate matter – IPXX rating per IEC 60529 = IPN_1N_2 (6.3 *)
  - N_1 = integer degree of protection against particulate matter (0 – 6 or X)
  - N_2 = integer degree of protection against ingress of water (0 – 8 or X)

*Step 3 – Classification (Cl. 6 *)*

- Method(s) of Sterilization (6.4)
  - MEE or its parts intended to be sterilized according to IFU method(s)
    - EtO, gamma, autoclave, etc.
- Suitability for use in an OXYGEN RICH ENVIRONMENT (6.5)
    - If MEE&S intended for such environment then classify as such.
- Mode of operation (6.6 *)
  - Either CONTINUOUS OPERATION or NON-CONTINUOUS OPERATION
- TRANSPORTABLE (MOBILE, PORTABLE, BODY-WORN, HANDHELD) VS. STATIONARY (FIXED) MEE&S (Definitions in Cl. 3 & See Figure A.20)

Step 4

Generate an Isolation Diagram
Early in development cycle

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Step 4 – Isolation (or Insulation) Diagram

- Diagram used in design to:
  - ID required insulation systems
    - Spacings (AIR CLEARANCE & CREEPAGE) & DIELECTRIC (hi-pot)
    - Allows MEE&S to be designed according to necessary insulation parameters at an early stage of design
    - ID alternate construction possibilities
    - Convey design criteria to Engineering, production staff & vendors (engineering drawings, specification sheets, etc.)

Step 4 – Isolation (or Insulation) Diagram Details

- MEE&S needs 2 MEANS OF PROTECTION (MOP's) to prevent APPLIED PARTS & OTHER ACCESSIBLE PARTS from exceeding limits specified in Cl. 8.4 (8.5.1.1)
- One MOP = Basic Insulation (BI)
- Two MOP = Double or Reinforced Insulation (DI/RI)
  - MEANS OF OPERATOR PROTECTION (MOOP): Need either 2 MOOP's (DI/RI) or 1 MOOP & protectively earthed parts (or impedance – not common)
  - Means of patient protection (MOPP): Need either 2 MOPP's (DI/RI) or 1 MOPP & protectively earthed parts (or impedance – not common)
- Make sure isolation provided is reliable and if use components for isolation certified appropriately
- Refer to Figure A.12 to understand MOOP vs MOPP – Appendix
- Example Isolation Diagram & Table of Requirements – Appendix

Step 5

1) Identify Critical Components,
2) Obtain Manufacturer Specification Sheets, Component Agency Certificates & Agency Test Reports

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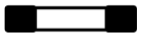
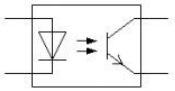
Step 5 – Critical Components

- Mains components
  - Power supplies (medical vs ITE) – internal & external (i.e. brick supplies)
  - Power cords (Country specific, EU = <HAR>)
  - Fuses (Mains, secondary if relied on for a safety test, etc.) 
  - Circuit breakers
  - Inlet receptacle 
  - Capacitors – Y1 & Y2
  - Switches in primary 
  - Line filters (EMI filters – designed for medical to KEEP LEAKAGE CURRENT low)
  - Relays (if in Primary or relied on for safety, etc.)
  - Fans  (if in Primary or relied on for safety)
  - Thermal protectors Etc....

Step 5 – Critical Components

- Isolation for Safety
  - Mains & Isolation transformers 
  - Opto-isolators 
  - Internal wiring
  - Insulation tubing & sleeving
  - Wire positioning devices
  - Etc.

Step 5 – Critical Components

- Flammable components

  - Printed circuit boards: Typically min flame rating of FV-2 (or UL 94V-2)
  - Plastics
    - Min FV-2 (or UL 94V-2) for TRANSPORTABLE MEE &
      Min FV-1 (or UL 94V-1) for FIXED or STATIONARY MEE
- Other Assorted Components
  - Lithium batteries 
  - Labelling material
  - Crimp connectors & other assorted connectors

Step 5 – Gather Critical Component Documentation

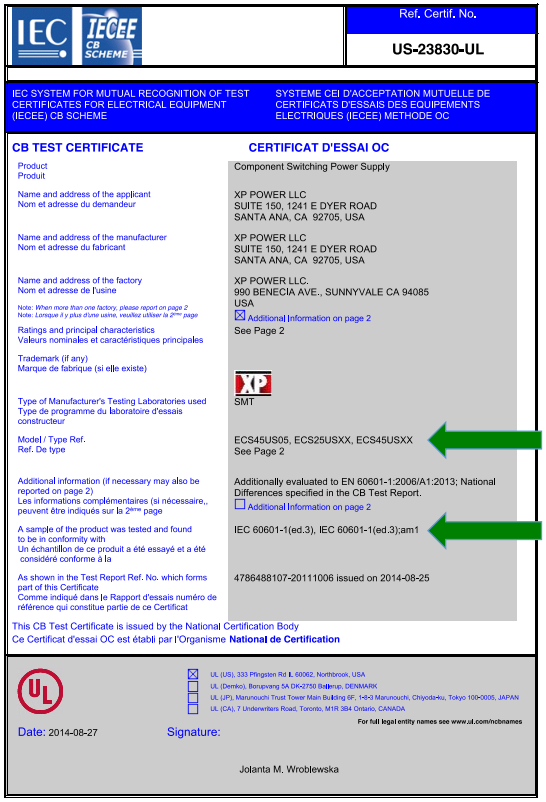
- Obtain documentation
  - Engineering specification sheet from component manufacturer
  - Engineering drawings
  - UL Recognized component certification for specific components
  - UL CoA's or similar for other Agency Reports
  - CSA component certification for specific components
  - Test certificates & TRFs from various other test lab(s) where product was tested
- Schematic flow chart for component qualification for IEC 60601-1 (Cl. 4.8, Fig 5) – Appendix

Step 5 – Gather Critical Component Documentation

- Obtain documentation
  - For power supplies need additionally:
    - Copy of CB certificate & test report (TRF) to IEC60601-1, ed. 3.0 or 3.1
    - CB certificate & TRF to IEC 60950-1 if device is completely outside patient environment or
      - meets criteria for SYSTEMS of Clause 16 & Annex I – ME SYSTEMS aspects – Combinations of MEE & non-ME EQUIPMENT
  - Critical project time line issues – Samples ready early for project
    - Sample of plastic enclosure – Mould stress & mechanical abuse tests
    - Label material – Durability & legibility tests, label review & approval process.

Step 5 – Critical Component Certificates/TRF's

CB Scheme Certificate



IEC IECEE CB SCHEME

Ref. Certif. No.

US-23830-UL

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE / **CERTIFICAT D'ESSAI OC**

Product / Produit	Component Switching Power Supply
Name and address of the applicant / Nom et adresse du demandeur	XP POWER LLC SUITE 150, 1241 E DYER ROAD SANTA ANA, CA 92705, USA
Name and address of the manufacturer / Nom et adresse du fabricant	XP POWER LLC SUITE 150, 1241 E DYER ROAD SANTA ANA, CA 92705, USA
Name and address of the factory / Nom et adresse de l'usine	XP POWER LLC. 990 BENECIA AVE., SUNNYVALE CA 94085 USA ☒ Additional Information on page 2
Ratings and principal characteristics / Valeurs nominales et caractéristiques principales	See Page 2
Trademark (if any) / Marque de fabrique (si elle existe)	XP
Type of Manufacturer's Testing Laboratories used / Type de programme du laboratoire d'essais constructeur	SMT
Model / Type Ref. / Ref. De type	ECS45US05, ECS25USXX, ECS45USXX See Page 2
Additional information (if necessary may also be reported on page 2) / Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page	Additionally evaluated to EN 60601-1:2006/A1:2013; National Differences specified in the CB Test Report. ☐ Additional Information on page 2
A sample of the product was tested and found to be in conformity with / Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1(ed.3), IEC 60601-1(ed.3);am1
As shown in the Test Report Ref. No. which forms part of this Certificate / Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	4786488107-20111006 issued on 2014-08-25

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

UL

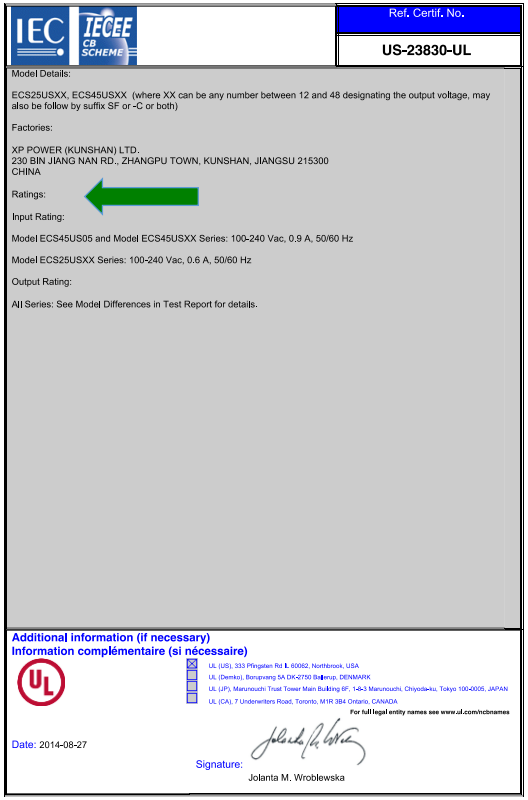
☒ UL (US), 333 Pfingsten Rd IL 60062, Northbrook, USA
☐ UL (Demko), Borupvang 5A DK-2750 Ballerup, DENMARK
☐ UL (JP), Marunouchi Trust Tower Main Building 6F, 1-8-3 Marunouchi, Chiyoda-ku, Tokyo 100-0005, JAPAN
☐ UL (CA), 7 Underwriters Road, Toronto, M1R 3B4 Ontario, CANADA

For full legal entity names see www.ul.com/ncbnames

Date: 2014-08-27 Signature:

Jolanta M. Wroblewska

1/2



IEC IECEE CB SCHEME

Ref. Certif. No.

US-23830-UL

Model Details:

ECS25USXX, ECS45USXX (where XX can be any number between 12 and 48 designating the output voltage, may also be follow by suffix SF or -C or both)

Factories:

XP POWER (KUNSHAN) LTD.
230 BIN JIANG NAN RD., ZHANGPU TOWN, KUNSHAN, JIANGSU 215300
CHINA

Ratings:

Input Rating:

Model ECS45US05 and Model ECS45USXX Series: 100-240 Vac, 0.9 A, 50/60 Hz

Model ECS25USXX Series: 100-240 Vac, 0.6 A, 50/60 Hz

Output Rating:

All Series: See Model Differences in Test Report for details.

Additional information (if necessary)
Information complémentaire (si nécessaire)

UL

☒ UL (US), 333 Pfingsten Rd IL 60062, Northbrook, USA
☐ UL (Demko), Borupvang 5A DK-2750 Ballerup, DENMARK
☐ UL (JP), Marunouchi Trust Tower Main Building 6F, 1-8-3 Marunouchi, Chiyoda-ku, Tokyo 100-0005, JAPAN
☐ UL (CA), 7 Underwriters Road, Toronto, M1R 3B4 Ontario, CANADA

For full legal entity names see www.ul.com/ncbnames

Date: 2014-08-27 Signature:

Jolanta M. Wroblewska

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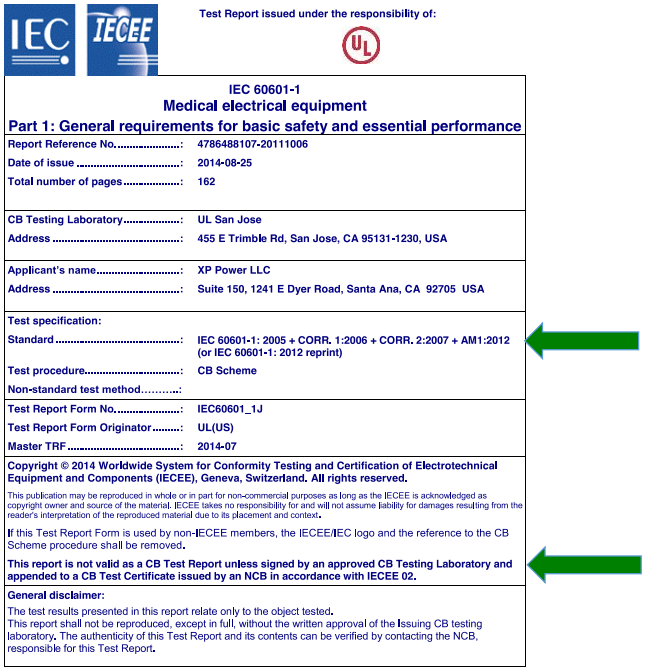
CB Scheme Test Report (TRF)



IEC IECEE

Test Report issued under the responsibility of:

UL

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.	4786488107-20111006
Date of issue	2014-08-25
Total number of pages	162
CB Testing Laboratory	UL San Jose
Address	455 E Trimble Rd, San Jose, CA 95131-1230, USA
Applicant's name	XP Power LLC
Address	Suite 150, 1241 E Dyer Road, Santa Ana, CA 92705 USA
Test specification:	
Standard	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure	CB Scheme
Non-standard test method	
Test Report Form No.	IEC60601_1J
Test Report Form Originator	UL(US)
Master TRF	2014-07

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This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

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Step 6

1) Identify Essential Performance (EP)
2) Prepare Draft of Risk Management File (RMF)

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Step 6 – Document Essential Performance

- Define & Document ESSENTIAL PERFORMANCE (EP) (Cl. 4.3*)
  - EP will impact test plan
- ESSENTIAL PERFORMANCE (EP, cl. 3.27*) definition
  - performance, of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable risk.
- EP process (Cl. 4.3*)
  - During RISK ANALYSIS, the MANUFACTURER shall identify the EP of the MEE&S (1st para of 4.3)
  - The MANUFACTURER shall specify performance limits between fully functional & total loss of the identified performance in both the NORMAL CONDITION & SINGLE FAULT CONDITION
  - Follow full process of Cl. 4.3

Step 6 – Document Essential Performance & Draft RMF

- ESSENTIAL PERFORMANCE (EP)
  - EP more likely when a critical care product (i.e. anesthesia, heart-lung machines, ICU monitors, etc.). Does apply to some less critical devices too
  - Changes in "intended use" can change EP of device
  - FDA: If your predicate device has EP then your device may need to show EP too, even if no EP for device
  - Particular Standards (60601-2-XX & 80601-2-XX) tend to have EP
- RISK MANAGEMENT PROCESS (RMP) (4.2.2)
  - RMP complying with ISO 14971 shall be performed & required
  - Ubiquitous in standard.
  - Therefore you can't comply with IEC 60601-1 ed. 3.0 or 3.1 without complying with ISO 14971

Step 6 – Draft RMF

- Opinion
  - RISK MANAGEMENT (RM) started in ed. 3rd as a way to evaluate equivalent safety (2nd ed. Cl. 3.4) (4.5*)
  - RM was seen as a way to get 3rd ed. standard finished even though detailed requirements weren't ready. RM used as "catch-all"
  - **End result was RM overload**
  - ed. 3.1 reduced the overload by about 20% for the Risk Management File (RMF) requirements

Step 6 –Draft RMF

- RISK MANAGEMENT FILE (RMF)
  - Use IECEE CB Scheme TRF & Lab paperwork for RMF
    - Current TRF version K, to document RMP (4.2.2) & RMF requirements of IEC 60601-1, ed. 3.1 to show compliance to standard
  - Many compliance statements in the standard say: "Compliance is checked by inspection of the RMF."

Step 6 – Risk Management File Steps

- Manufacturer puts together all the RMP (ISO 14971) & RMF documents
- Manufacturer provides “map” with RM requirements filled in TRF rev k
- Do documents show that process fully meets the standard?
- Expect process take 30 days of 1 person’s time to complete approx. 100 or 125 RMF references in IEC 60601-1 (ed. 3.1 or ed. 3.0 respectively)

Step 6 – Draft RMF

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM		
	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See appended Tables 11.6.1; 8.7, 8.8.3 and **RMF Reference to specific RISK:** **(ISO 14971 Cl. __)**	

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
3.1		—	Risk Management Process (excluding production and post-production)	
3.2		—	Adequate Resources	
3.2		—	Assignment of qualified personnel	
3.2		—	Policy for determining criteria for risk acceptability	
3.3	—		Qualification of personnel	
3.4a	—			
3.4b	—			
3.4c	—			
3.4d	—			
3.4e	—			
3.5	—			
4.1	—			
4.2	—			
4.3	—			
4.4	—			
5	—			
6.2	—			
6.3	—			
6.4	—			
6.5	—			
6.6a	—			
6.6b	—			
6.7	—			
7	—			
8	—			

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Step 7

Draft Test Plan

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Step 7 – Draft Test Plan

- 60601 Series based on TYPE TESTING
  - Type Test (3.135, 5.1*) – Test on a representative sample of MEE&S with objective of determining if device, as designed & manufactured can meet requirements of standard
- Identify all applicable tests in a draft test plan
  - One test plan can accommodate > 1 standard & 1 product

Product 1	Product 2	Clause in IEC 60601-1, 3.1 ed.	Clause in IEC 60601-2-33 (3rd ed. + A1?)	Test Name	Test # per / Page in AAMI IEC/TR62354	Comments
√	√	4.2, 4.5	--	RISK MANAGEMENT PROCESS Alternative Risk Control measures or test methods for M.E.E. or M.E.S.	13.2.1 / 11	4.2 Follow the process detailed in all of 4.2 of ed 3.1 of IEC 60601-1. 4.5 – Use if needed because can't meet a requirement as stated in standard but can show still safe using Risk Management Process.

Step 7 – Draft Test Plan

- EP & RMF will impact test plan (See Step 6)
- Remarks for specific tests to help understand important details
  - Remarks can be ratings info, classification details, details about the device, the installation, positioning of device, etc.
- Justify tests not conducting. Why are they N/A?
- Understand tests so your design meets the tests. Pre test (Step 13)

Step 8

Labelling & Marking Requirements
Review Labelling & Markings Meet Requirements

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Step 8 – Labelling & Marking Review Steps

- Review all marking on/in your device against requirements
  - Symbols, safety signs, switches, units of measure
- Review IFU's / Quick Start Guides / Etc.
- Review Technical Description (Service Manual)
  - Many service manuals now embedded in IFU's
- Did you review requirements in applicable Collaterals and Particular standards?
  - i.e. IEC 60601-1-2, -1-11, -1-12
    - -1-11 (Home Use) has education level readability requirements of Manual
  - Particular Standards have some to a lot of requirements

Step 8 – Labelling & Marking Requirements

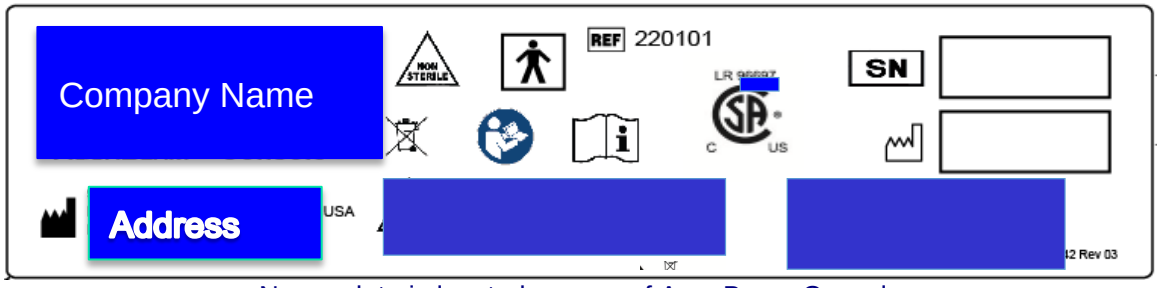
- Accompanying documents includes in Cl. 7.9:
  - General requirements
  - Instructions for Use (IFU)
  - Technical descriptions (i.e. Service Manual)
- IFU for
  - OPERATOR
  - RESPONSIBLE ORGANIZATION
- Technical Description for
  - RESPONSIBLE ORGANIZATION
  - SERVICE PERSONNEL
- Annex C – All other references outside of Cl. 7 to Marking and Labeling Requirements – See Appendix for Examples

Step 8 – Labelling & Marking Requirements

- Legibility of markings Test (7.1.2*)
  - Requirements w.r.t. intended position of OPERATOR to MEE&S
  - Test conditions include 20/20 vision & able to read line N6 from Jaeger test card in normal room lighting (500 lx)
- Durability of marking Test (7.1.3*)
  - Rub Test to ensure required labels / markings don't get rubbed off or that labels don't peel up or fall off device

Step 8 – Labelling & Marking Requirements

- Outside & inside markings (7.2 & 7.3)



IPXX rating?

100V-120V~, 50/60Hz, 4.0A

230V ~, 50/60Hz, 1.8A

- Markings on controls and instruments (7.4)
  - Power switches, control devices, units of measure

Step 8 – Labelling & Marking Requirements

- Safety signs (7.5) vs symbols (7.6) 

	Caution = Black & White Symbol (**used to be** "Consult accompanying documents"). ***Since colored is a Safety sign & now means General Warning now***
	Refer to instruction manual booklet
	Operating instructions for use

Step 8 – Labelling & Marking Requirements

- 7.2.3* - Consult ACCOMPANYING DOCUMENTS symbol changed from 2nd  to 3rd ed.:

		
ISO 7000-1641	IEC 60878 Safety 01!	ISO7010-M002!

! Use this symbol if mandatory action required as a Risk Control Measure per 7.2.3

- Appendix - Corrigendum 1 (Dec 2006) Change

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Step 8 – Labelling & Marking Requirements

- Indicator lights & controls (7.8*)
- Indicator color lights (7.8.1)
  - Color of lights harmonizes with IEC 60601-1-8 - Medical Alarms

Table 2 of IEC 60601-1

Red	Warning – Immediate Operator response required
Yellow	Caution – Prompt Operator response required
Green	Ready for use
Other	Other than above

Step 9

Construction Review

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Step 9 – Construction Review

- Does the device meet all the constructional requirements of the General Standard IEC 60601-1?
  - Spacings review against isolation diagram & table of requirements
  - Power supply(ies) & transformer(s) meet spacings, thru insulation requirements, etc. – Proper materials used (class, etc.)?
  - Cl. 15 – physical construction requirements
  - Review applicable tests - will id some construction requirements you need to meet (i.e. protective earth grounding, wiring, enclosure material requirements, openings, etc.)

Step 9 – Construction Review

- Review the General Standard for constructional requirements
  - Use TRF to capture this info
  - Review all component info & meet proper standards – Step 5
  - Is your isolation diagram up to date with current design
    - If not update & make sure you design meets standard(s)
  - Is your test plan up to date & cover all applicable tests?
    - Have you reviewed tests to make sure understand the implications on your design?
  - Marking & labelling do they meet the standard – Step 8?

Step 9 – Construction Review

- Review the General Standard for constructional requirements
  - Review RMF & EP compliance info for any constructional requirements – Steps 6 & 12
  - Review system requirements of Cl. 16 – any impact?
  - Review PEMS requirements of Cl. 14 – any impacts?
  - Review EMC requirements of Cl. 17 – any impacts?
- Review Collateral & Particular Standards for constructional requirements – Any other standards?

Step 10

Test Labs
What to Consider

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Step 10 – Test Lab Considerations

- Does your company have a test lab?
  - Used only for pre-testing or
  - certified by safety test lab
- Are you locked into a lab?
- Do you like the current lab you are working with?
- What are your looking for in a test lab?
  - Solid test report(s) to support your regulatory submission(s)?
  - Experts in specific tests (i.e. Particulars & Collaterals)
  - Convenience of a local lab?
    - Drop off spare parts, fix a damaged board, see testing run, etc.

Step 10 – Test Lab Considerations

- What are your looking for in a test lab?
  - Is your product portable & you want fastest option?
    - Opens up options
  - Reputation matter to you?
  - Does cost matter?
  - Want a lab that is flexible but still meets intent of standards?

Step 10 – Test Lab Considerations

- What are your looking for in a test lab?
  - Some labs will ship testing to other locations – ask if lab you are talking to will do that & if you have recourse
  - Watch out for testing in certain Asian markets
    - Seen some horrible reports
  - Does your company have other concerns?

Step 11

Request for Quote(s) (RFQs)

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Step 11 – Obtain Quotes (RFQs)

- Provide lab with appropriate info for accurate quote:
  - Otherwise costs could increase, test times could take longer, wrong test standards could be used, etc.
  - Identify all applicable standards to be tested too
  - Identify product(s), product versions, product families to be tested
  - Fill out their RFQ form – typically asks for:
    - Device description & Intended use
    - Model number(s)
    - Classification info per IEC 60601-1
    - Power & coolant requirements, etc.

Step 11 – Obtain Quotes (RFQs)

- Provide lab with appropriate info for accurate quote:
  - Fill out their RFQ form – typically asks for:
    - What countries do you need certification for
    - Any national deviations
    - Do you need a CB scheme report (TRF but thru CB process) & certificate
      - Do you need certification mark from > 1 test lab
        - has expense to it
      - < expensive – TRF without certificate (Not official CB Scheme)
    - Do you need a NRTL report

Step 11 – Obtain Quotes (RFQs)

- Provide lab with appropriate info for accurate quote:
  - Fill out their RFQ form – typically asks for:
    - IFUs, quick start guides, & service manual(s) – drafts ok
    - Block diagram(s)
    - Schematics
    - Isolation diagram, if available is really helpful
    - Component info – especially certificates, test reports, & CofA's for critical items
      - i.e. power supplies, transformers, mains components & isolation components, etc.

Step 11 – Obtain Quotes (RFQs)

- Provide lab with appropriate info for accurate quote:
  - Fill out their RFQ form – typically asks for:
    - Applied Part details – How many, what classifications, etc.
    - Does product have to be sterilized, cleaned, disinfected?
    - Alarms provided?
    - Home Use or Emergency Medical Services Environments?
    - Dimensions, weight, multiple configurations
    - Etc.

Step 11 – Obtain Quotes (RFQs)

- Any special requests of lab:
  - Fast turn around
  - Can lab conduct specialized tests of Particulars or Collaterals
  - Heavy equipment
  - Test at your location or on site testing
  - Etc.

Step 12

Finalize Risk Management File & Essential Performance

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Step 12 – Finalize RMF & Update Risk Analysis

- Finalize RMF & update RISK ANALYSIS (RA), as needed
  - Make sure to review text of standard – not just TRF wording (summary at best)
  - Prove meets ISO 14971 other than production and post-production are exempt per IEC 60601-1 (ed. 3.0 or 3.1)
  - RMF impacts RA – make sure RA updated to reflect RMF input before submit to test house

Step 12 – Finalize Essential Performance

- Finalize ESSENTIAL PERFORMANCE
  - Should have write up that is clear what the EP is and how confirm for each clinical function that is EP
  - The more complex the EP is can impact test time as many tests need to confirm EP as a criteria for compliance

Step 13

Pre-Testing Device(s)

Step 13 – Pre-Testing Device(s)

- Do as much pre-testing as possible
  - In house or at a test lab?
  - Put a test plan together for your comfort level
    - Humidity Testing 2 vs 7 days – Is it worth it for Pre-Testing?
    - If similar to past device some pre tests
    - If new concept more pre tests
    - If not comfortable with the standard(s) rely on test lab or a consultant to assist
      - Recommendation: Understand tests well enough & costs/timing so meets your needs (comfort level)

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Step 13 – Pre-Testing Device(s)

- If test failures
  - Do you need to redesign?
  - Does redesign impact?
    - Critical components
    - Isolation diagram & table of requirements
    - Product classification, labelling & marking
    - ESSENTIAL PERFORMANCE
    - RISK MANAGEMENT FILE
    - Test plan, project plan
    - Test lab quote, etc.

Step 14

What needed for Testing?
& Critical Time Line Items

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Step 14 – What Needed for Testing?

- What do you need to prepare for EMC Testing?
  - Provide samples:
    - Typically 1 functional device but good for back-up(s)
    - Spare parts – fuses, power supplies, populated PCBs, spare accessories, etc.
    - EMC mitigation supplies _filters, beads, etc.
    - EMC Labelling & Markings
      - Most EMC labs don't understand or know of EMC Labelling requirements so either you do your self or rely on a good EMC test lab.

Step 14 – What Needed for Testing?

- What do you need to prepare for Safety Test Agency (i.e. CSA, UL, ITS, TÜV's, etc.)?
  - Provide samples:
    - 1 or > fully functional device(s)
      - Thermoplastic enclosures & label samples
    - Spare parts – fuses, power supplies, populated PCBs, spare accessories, etc.
    - Markings
      - Can be drawing, if provide, at least representative label
      - Draft ok

Step 14 – What Needed for Testing?

- Provide documentation:
  - IFU, quick start guides, service manuals
  - RMF per Lab forms & TRF + supporting documentation
  - Components mentioned in Step 5
    - Engineering specification sheet from component manufacturer
    - Engineering drawings
    - UL Recognized component certification for specific components
    - CSA component certification for specific components
    - Test certificates & TRFs from various other test lab(s) where product was tested

Step 14 – What Needed for Testing?

- Provide documentation:
  - Components mentioned in Step 5
    - For power supplies need additionally:
      - Copy of CB certificate & test report (TRF) to IEC60601-1, ed. 3.0 or 3.1
      - CB certificate & TRF to IEC 60950-1 if device is completely outside patient environment or meets criteria for MEE&S of Annex I – ME SYSTEMS aspects – Combinations of MEE & non-ME EQUIPMENT

Step 14 – Critical Time Line Issues?

- Critical project time line issues
  - RMF per Lab forms & TRF + supporting documentation
  - All marking & labelling materials – Durability & legibility tests, label review
  - Sample of plastic enclosure – Mould stress & mechanical abuse tests
  - Certification mark approval process for some Agencies

Step 14 – What Needed for Testing?

- Critical project time line issues
  - Signed agreements with test lab(s)
  - Agent authorization paperwork, if using Agent / Consultant
  - Providing lab with deposit, if requested
  - Component certification info
  - Factory inspection paperwork, if initial certification with Test Lab
    - Have you set-up your production line test equipment for meeting IEC 60601-1?

Step 15

Communication with
Test Lab(s)
End Results

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Step 15 – Follow-Up – Communication

- Agree on start & end dates for:
  - testing / project,
  - construction review and preliminary review (pre certification testing), if requested,
  - project handler review of RMF,
  - project handler finalize report & test certificate,
  - certification mark approval,
  - additional information & / or samples for testing,
  - initial factory inspection
- Check in a couple times during project
  - make sure project on track instead of waiting til end date when delays impact critical path

Step 15 – Follow-Up – Communication & End Results

- If test failures, construction issues & / or labelling review issues, etc. – lab's options:
  - Put project on hold
    - Provide a status update & ask for client resolution of issues by deadline date or close project
    - May ask for a cost limit increase, additional samples & info to continue
  - Close project
    - Issue a letter report with current issues
      - new project for $____ (If can estimate – may wait for response) & ask to provide additional info, samples, resolve open issues, etc.
  - Well planned projects doing all steps can hit some bumps so plan for ____ weeks buffer in project plan

Step 15 – End Results

- If device meets requirements & tests – lab will issue:
  - Test report (either CB Scheme TRF or descriptive report, typically)
  - Agency certification info (certificate or directory listing)
  - Approve certification label, if required
  - Initial production inspection request
  - Request for special periodic testing of product or sub-system if component not certified under some standard previously (i.e. plastics, labelling, conductive coating, etc.)

Step 16

After Success of Certification – Don't Get Lazy Now

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Step 16 – Review Final Reports & Certificates

- Review all final reports & certificates for:
  - Typos, incorrect component info, wrong description of device, proper classifications, isolation diagram accurate, missed tests, wrong test configurations, wrong references to labelling/product, confirm no failing results, are N/A requirements marked appropriately, etc.
  - Advise lab if any mistakes within a 2 – 4 week window otherwise lab may want to charge for any changes requested

Resources

To reduce project delays

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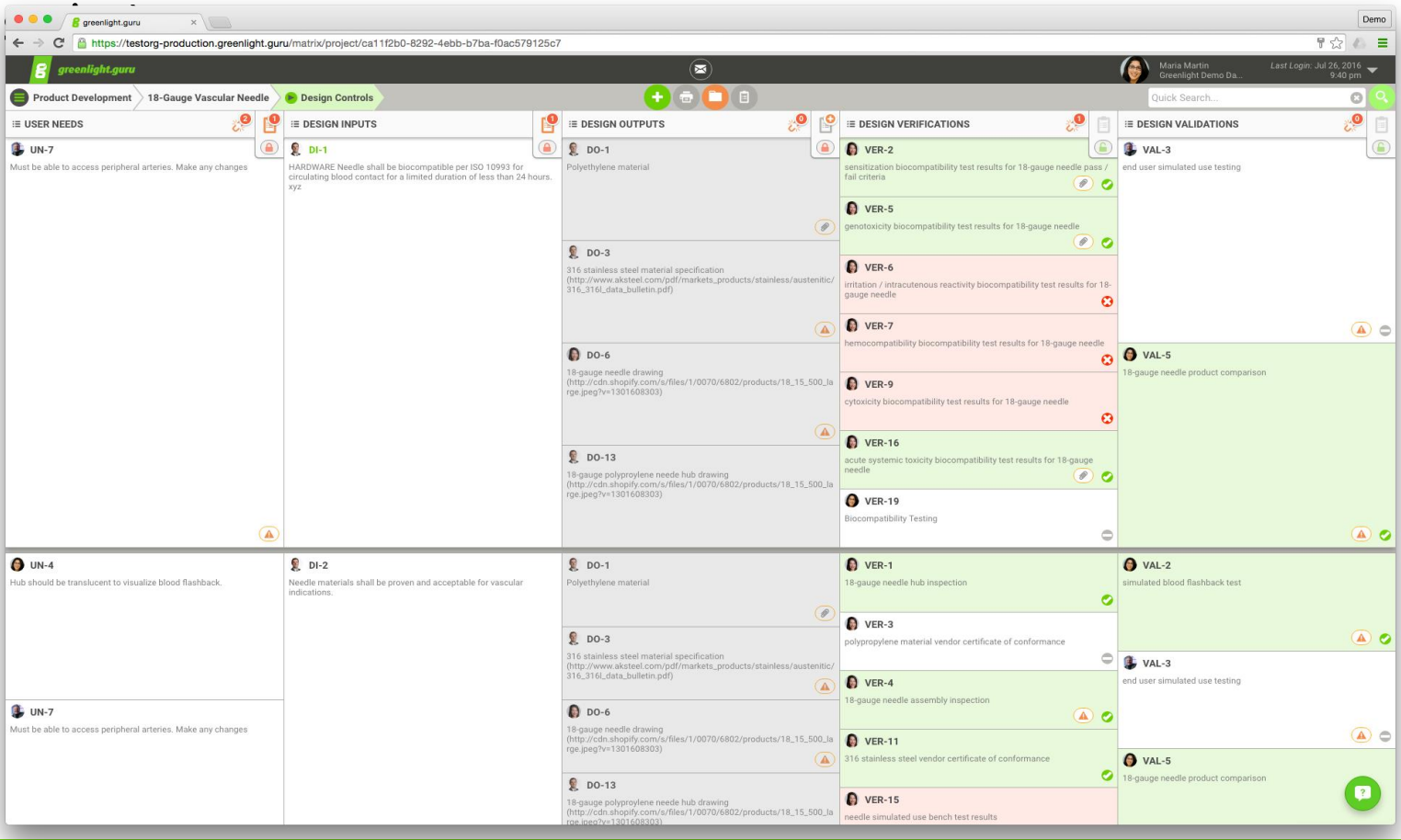
Resources to Reduce Project Delays

- Do a gap analysis between old & new requirements
- Do a preliminary review of device with test lab or consultant, especially if a novel design, for proper prep, etc.
  - Typically ½ to 1 day meeting to ask questions or get feedback on issues of product against standard – focus on what you need to understand
- Do a construction review (step 9) of device
  - If not comfortable use a consultant that knows standard well
- Proper leg work up front (15 steps above)
- Consultant up front review & support through out the process

Resources to Reduce Project Delays

- Use software tools to track your design requirements (60601



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Resources to Reduce Project Delays

- Do you know what standards will be changing & when?
  - IEC 60601-1, 3rd ed. + A2 (Draft) is in process & more to come
    - Do you have an early warning system in place to be able to strategically plan your product development & regulatory strategies?
    - How can you reduce your overhead (costs & time) to get inside information from standards committees?
    - Would you rather spend $20,000 for this information, even $100,000 or more for product redesign or pay for a yearly report to keep you updated?
    - **The answer is:** Our Annual Standards Trends Reports on MEE&S & Home Use MEE&S? ***Free Sample Report***
    - ***Special Webinar discounts good til 20 Jan '17***

Resources to Reduce Project Delays

Eisner Safety Consultants
Annual Standards Trends Reports on MEE&S &
Home Use MEE&S Options

Get This Year's Report(s): March 2017 Annual Standards Trends Report (ASTR) Options:

Was ~~$3,500.00~~ **Now only ~~$1,997.00~~ Webinar Special $1,597.00** for the:

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Get This & Last Year's Report(s): March 2016* & 2017 ASTRs Options:

Was ~~$6,500.00~~ **Now only ~~$2,397.00~~ Webinar Special $1,997.00** for the:

March 2016* & 2017 Medical Electrical Equipment & Systems (MEES) ASTRs **OR**
March 2016* & 2017 Home Use MEES ASTRs

Was ~~$11,500.00~~ **Now only ~~$3,697.00~~ Webinar Special $2,997.00** for the:

Bundle pricing for all 4 Reports - March 2016* & 2017 of both MEES & Home Use MEES ASTRs

* = MAR '16 ASTRs issued as of MAR '16 with no updates for these ridiculously low rates.

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Resources to Reduce Project Delays

Eisner Safety Consultants
Annual Standards Trends Reports on MEE&S &
Home Use MEE&S Options

Get Last Year's Report(s): March 2016* ASTRs Options:

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March 2016* Medical Electrical Equipment & Systems (MEES) ASTR **OR**
March 2016* Home Use MEES ASTR

Was ~~$6,500.00~~ **Now only ~~$1,197.00~~ Webinar Special $997.00** for the:

Bundle pricing for both the March 2016* MEES & Home Use MEES ASTRs

* = MAR '16 ASTRs issued as of MAR '16 with no updates for these ridiculously low rates.

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Where to Get More Information

- IEC 60601-1

http://www.EisnerSafety.com

http://www.EisnerSafety.com/Induystry_News

https://webstore.iec.ch/publication/2612 (Ed 3.1)

- Certification Safety Agencies & 3rd Party Test Houses

http://www.eisnersafety.com/links/

- Standards Organizations

http://www.eisnersafety.com/links/

- Standards Sales Organization

http://www.eisnersafety.com/links/

- Certification databases

http://www.eisnersafety.com/links/

Questions

What other 60601 series questions can we answer?

Leo@EisnerSafety.com

Appendix

Supplemental Info from Webinar
Examples, Diagrams, etc.

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IEC 60601-1 Basics

The IEC 60601 Series too

Collateral Standards

- 60601-1-1 – **Withdrawn** Electrical Medical Systems
  - Now in Cl. 16 of 60601-1, ed. 3.0 & 3.1
- 60601-1-2 – EMC (3rd ed.) or EM Disturbances (4th ed.)
  - FDA, EU & Health Canada aligned transition date for 4th ed.
    - End of use of 3rd ed. on 31 Dec 2018
  - Exception for US is Home Use Guidance asks for 4th ed.
- 60601-1-3 – Radiation protection in diagnostic X-ray equipment (ed. 2.1, CSV)
- 60601-1-4 – **Withdrawn** PEMS
  - Now in Cl. 14 of 60601-1, ed. 3.0 & 3.1
- 60601-1-5 – **Never published** (Merged into another doc) Image quality & dose for x-ray equipment

Collateral Standards

- 60601-1-6 – Usability (ed. 3.1 CSV)
  - Doesn't include post-production monitoring & periodic maintenance of the Usability Engineering Process like IEC 62366 does.
  - Many labs using IEC 62366 as many regulators requiring currently
- 60601-1-7 – **Never Published** Standard number re-assigned - probably assigned to 60601-2-49 (multifunction patient monitoring equipment)
- 60601-1-8 – Alarm systems (ed. 2.1 CSV)
- 60601-1-9 – Environmentally conscious design (ed. 1.1 CSV)
- 60601-1-10 – Physiologic closed-loop controllers (ed. 1.1 CSV)
- 60601-1-11 – Home healthcare environment (2nd ed. RLV)
- 60601-1-12 – Emergency medical services environment (1st ed.)

Step 2

OD-2055 IECEE CB Scheme
Helpful tool for Collaterals selection

OD-2055 for 60601-1, 2nd ed., Collateral Selection Tool

Annex A Use of Standards in the IECEE system according to the IEC 60601-1 2nd edition

IEC 60601-1 2nd edition (including Am. 1 & Am. 2) for Medical Electrical Equipment – Part 1: General Requirements for Safety	Collateral and Related standards Required to be included in CBTC		Acceptable to issue a separate CBTC and CBTR	
Standards	**Yes**	**No**	**Yes**	**No**
IEC 60601-1-1, ed. 2:2000, Medical electrical equipment - Part 1-1: General requirements for Safety - Collateral standard: Safety requirements for medical electrical systems	X			X
IEC 60601-1-2, ed. 2:2000 and Am.1:2004, Medical electrical equipment - Part 1-2: General requirements for Safety - Collateral standard: Electromagnetic compatibility - Requirements and tests		X	X	
IEC 601-1-3, ed1:1994 Medical electrical equipment - Part 1-3: General requirements for Safety - Collateral Standard: Radiation protection in diagnostic X-ray equipment	X			X
IEC 60601-1-4, ed1:1996 and Am.1:1999, Medical electrical equipment - Part 1: General requirements for Safety - Collateral standard: Programmable electrical medical systems		X		X
IEC 60601-1-6, ed1:2004, Medical electrical equipment - Part 1-6 General requirements for Safety - Collateral standard: Usability		X		X
IEC 60601-1-8, ed1:2003 and Am.1:2006, Medical electrical equipment - Part 1-8: General requirements for Safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	X			X
ISO 10993-1, ed. 3:2003 – Biological evaluation of medical devices — Part 1: Evaluation and testing		X		X

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OD-2055 for 60601-1, 3rd ed. , Collateral Selection Tool

Annex B Use of Standards in the IECEE system according to the IEC 60601-1 3rd edition

IEC 60601-1 3rd edition (2005-12), Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance	Collateral & Related Standards Required to be included in CBTC		Acceptable to issue a separate CBTC and CBTR	
Standards	**Yes**	**No**	**Yes**	**No**
IEC 60601-1-2, ed. 3:2007, Medical electrical equipment - Part 1-2: General requirements for Basic Safety and essential performances - Collateral standard: Electromagnetic compatibility - Requirements and tests		X	X	
IEC 60601-1-3, ed. 2:2008, Medical electrical equipment - Part 1-3: General requirements for Basic Safety and essential performances- Collateral Standard: Radiation protection in diagnostic X-ray equipment	X			X
IEC 60601-1-6, ed. 2:2006, Medical electrical equipment - Part 1-6 General requirements for Basic Safety and essential performance - Collateral standard: Usability Note: IEC 60601-1-6 edition 2 or edition 3 apply as determined by national requirements		X*		X
IEC 60601-1-6, ed. 3:2010, Medical electrical equipment - Part 1-6 General requirements for Basic Safety and essential performance - Collateral standard: Usability, and IEC 62366 ed.1:2007, Medical devices – Application of Usability Engineering to Medical Devices		X*		X
IEC 60601-1-8 ed. 2:2006, Medical electrical equipment - Part 1-8: General requirements for Basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	X			X
IEC 60601-1-9, ed. 1:2007, Medical electrical equipment - Part 1-9: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design		X		X
IEC 60601-1-10, ed. 1:2007, Medical electrical equipment - Part 1-10: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers	X			X
IEC 60601-1-11, ed. 1:2010, Medical electrical equipment - Part 1-11: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	X			X
ISO 10993-1, ed. 4:2009, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process		X		X

*Note 1: Any CB Test Report addressing Collateral standards IEC 60601-1-11 and IEC 60601-1-8 requires Usability Engineering Process according to IEC 60601-1-6. This is due to the fact that the primary concern of home health care applications (IEC 60601-1-11) and alarms (IEC 60601-1-8) is whether the users and patients respond appropriately to the medical device equipment; this is mitigated through the Usability Engineering Process of the IEC 60601-1-6 standard.

Note 2: All applicable collateral standards must be included in the CB Test Report when applicable.

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OD-2055 for 60601-1, 3rd ed. + A1, Collateral Selection Tool

Annex C Use of Standards in the IECEE system according to the IEC 60601-1 3rd edition and Am.1

IEC 60601-1 3rd edition (2005-12), Am. 1 (2012), Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance	Collateral & Related Standards Required to be included in CBTC		Acceptable to issue a separate CBTC and CBTR	
Standards	**Yes**	**No**	**Yes**	**No**
IEC 60601-1-2, ed.3:2007 or IEC 60601-1-2, ed.4:2014, Medical electrical equipment - Part 1-2: General requirements for Basic Safety and essential performances - Collateral standard: Electromagnetic compatibility (ed.3) / disturbances (ed.4) - Requirements and tests		X	X	
IEC 60601-1-3, ed.2:2008 or IEC 60601-1-3, ed.2:2008 and Am1:2013, Medical electrical equipment - Part 1-3: General requirements for Basic Safety and essential performances- Collateral Standard: Radiation protection in diagnostic X-ray equipment	X			X
IEC 60601-1-6, ed.2:2006 or IEC 60601-1-6, ed.3:2010 or IEC 60601-1-6, ed.3:2010 and Am1: 2013, Medical electrical equipment - Part 1-6 General requirements for Basic Safety and essential performance - Collateral standard: Usability IEC 62366, ed.1:2007 or IEC 62366, ed.1 and Am1:2014, Medical devices – Application of Usability Engineering to Medical Devices	X			X
IEC 60601-1-8, ed.2:2006 or IEC 60601-1-8, ed.2:2006 and Am.1:2012, Medical electrical equipment - Part 1-8: General requirements for Basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	X			X
IEC 60601-1-9, ed.1:2007 or IEC 60601-1-9, ed.1:2007 and Am.1:2013, Medical electrical equipment - Part 1-9: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design		X		X
IEC 60601-1-10, ed.1: 2007 or IEC 60601-1-10, ed.1:2007 and Am.1:2013, Medical electrical equipment - Part 1-10: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers	X			X
IEC 60601-1-11, ed.1:2010, Medical electrical equipment - Part 1-11: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	X			X
ISO 10993-1, ed.4:2009, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process		X		X
IEC 62304, ed.1:2006, Medical device software – Software life cycle processes	X*			X

Note 1: All applicable collateral standards must be included in the CB Test Report when applicable

*Note 2: Applicable clauses of IEC 62304 must be addressed in the CB Test Report but the standard IEC 62304 is not to be listed on the CB Test Certificate

Note 3: Alternative editions (including amendments) of the standards listed above apply as determined by national requirements

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Step 3

Relationship Between Transportable & Stationary Equipment (Fig A.20)

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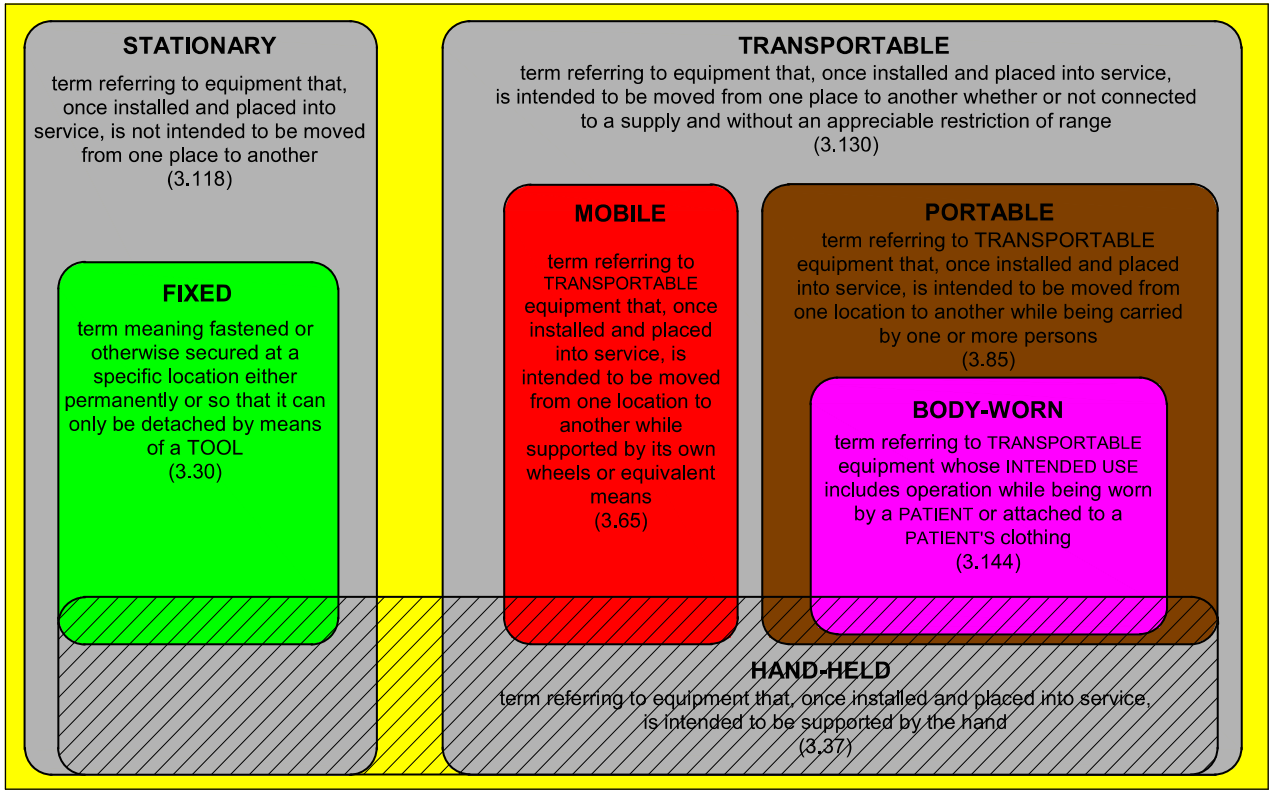
Step 3 – Relationship Between Transportable & Stationary Equipment (Fig A.20)



IEC 1422/12

Step 4

Isolation
Example Isolation Diagram &
Table of Requirements

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Step 4 – Isolation MOOP vs MOPP

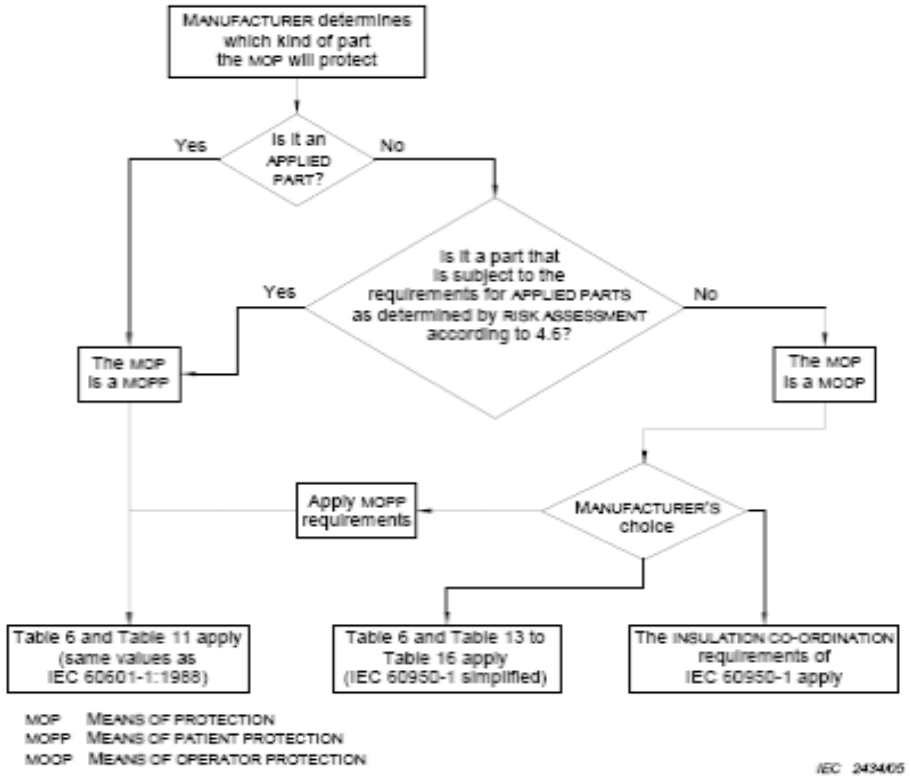
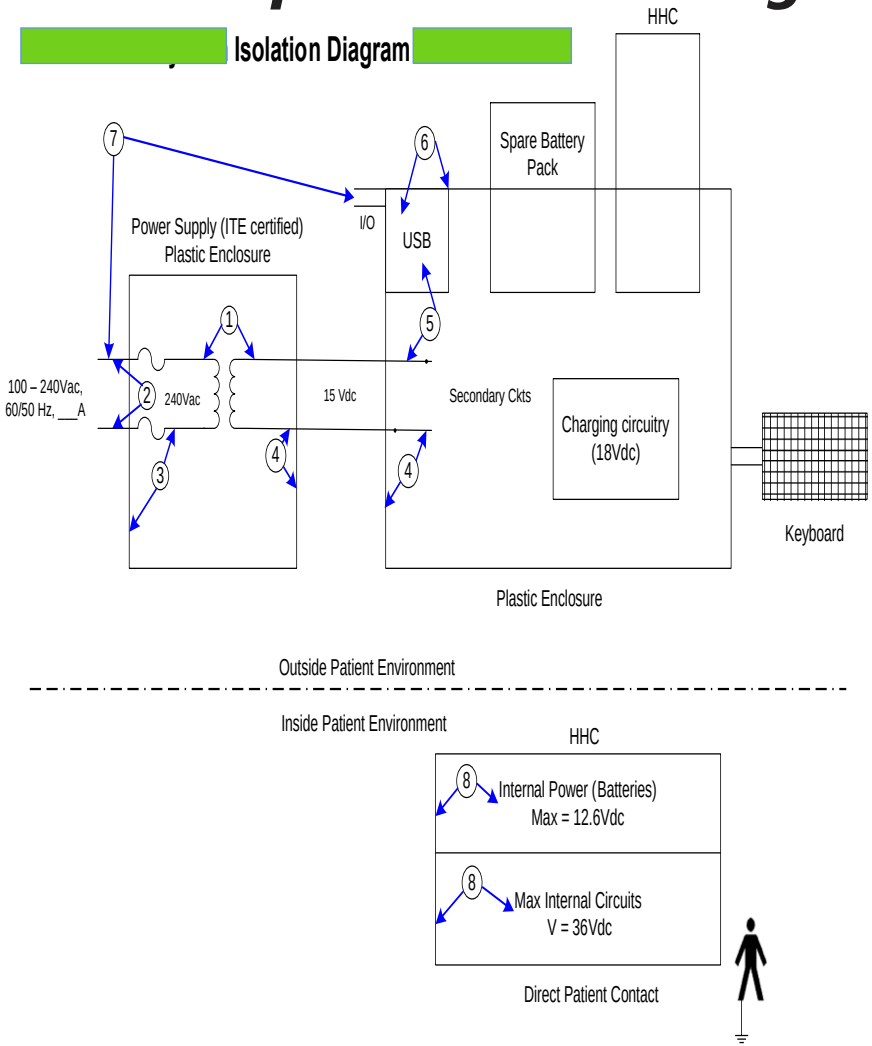


Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION

Step 4 – Example Isolation Diagram



Step 4 – Example Isolation Table

INSULATION TABLE for XXXXX System

					Requirements										
Item	Description	Working Voltage	Insulation Type	Means of Protection (3rd ed.) (Either Means of Operator or Means of Patient Protection = MOOP or MOPP)	Creepage over surface (mm) (8.9.1.1 - 8.9.1.15)	Creepage Table Used (3rd ed Tables 12 - 16)	Creepage Adjusted based on 8.9.1.4	Modified Creepage (mm)	Air Clearance (mm) (8.9.1.1 - 8.9.1.15)	Air Clearnace Table Used (3rd ed.) (Tables 12 - 16)	Air Clearance Multiplication Factor for elevation > 2K meters per 8.9.1.5 (Table 8)	Adjusted Air clearnace	Hi-Pot (Dielectric) (volts) (Table 6 or 7)	Through Insulation (Refer to 8.8.2)	Remarks
								CC							
--	Power Supply for CC	See remarks													Either use a Certified ITE (Information Technology Equipement) power supply or meet requirements of items 1 - 4. ITE certified power supply needs IEC 60950-1, UL 60950-1, CAN/CSA C22.2 No. 60950.1
1	Mains (Primary) to Secondary Circuits	240Vac	Two Levels	MOOP	**5**	16	No	--	**4**	13	1	4	**3000**	**Yes, refer to 8.8.2**	Using a certified Information Technolgy Equipment Grade power source to IEC 60950-1, UL 60950-1 and CAN/CSA c22.2 No. 60950.1
2	Between Opposite Polarities of Mains (Primary)	240Vac	--	Operator	**3**	11	No	--	**1.6**	11	1	1.6	N/A	No	If creepage and/or air-clearance do not meet the spacings requirements than can do a short circuit & if fuse blows quickly and causes no other hazards then acceptable per 8.9.2a). But need to meet these spacings requirements up to the over-current device.
3	Primary (Mains) to plastic enclosure	240Vac	Two Levels	MOOP	**5**	16	No	--	**4**	13	1	4	**3000**	**Yes min 0.4mm**	The enclosure has no exposed metal.
4	Secodnary to plastic enclosure	≤18Vdc	Two Levels	MOOP	~~2.4~~	16	Yes	**4**	**4**	13 (refer to 8.9.1.12 3rd para)	1	4	N/A	No	The enclosure has no exposed metal. Modified Creepage distance needs to be applies so the Creepage distance per Table 16 is over-ridden by clause 8.9.1.4
5	Secondary to USB or computer connection (SIP/SOP)	50Vdc	Two Levels	MOOP	~~2.4~~	16	Yes	~~4~~	~~4~~	13 (refer to 8.9.1.12 3rd para)	1	4	957	No	For Item 5 there are two lines as there are two conditions to look at. The boxed and bolded items of the two lines are to worse case that needs to be applied. UL assume a min of 50V working voltage on SIP/SOP unless you specify the specific device connected to.
		250V	Two Levels	MOOP	**5**	16	No	--	**4**	13 (refer to 8.9.1.12 3rd para)	1	4	**1980**	**Yes, refer to 8.8.2**	For Item 5 there are two lines as there are two conditions to look at. The boxed and bolded items of the two lines are to worse case that needs to be applied. Refer to 8.1a) first bullet. 8.1a) first bullet is considered a normal condition. This normal condition is assuming that there may be a failure on the computer (even if certified) than would be equivalent to the mains voltage.
6	USB or computer connection (SIP/SOP) to plastic enclosure	250V	Two Levels	MOOP	**5**	16	No	--	**4**	13 (refer to 8.9.1.12 3rd para)	1	4	**1980**	**Yes, refer to 8.8.2**	Refer to 8.1a) first bullet.
7	Mains (Primary) to USB or computer connection (SIP/SOP)	250V	Two Levels	MOOP	**5**	16	No	--	**4**	13 (refer to 8.9.1.12 3rd para)	1	4	**1980**	**Yes, refer to 8.8.2**	Refer to 8.1a) first bullet.
								HHC							
8	Secondary Circuits to Patient Applied Part (Enclosure)	≤36Vdc	Two Levels	MOPP	**4**	12	No	--	**2**	12	1	2	**1000**	No	Note per Table 12 can go up to 43Vdc and the requirements would be the same. If go up to 85Vdc would be creepage 4.6mm and air clearance of 2.4mm. Of all three rows of item 8 this is the most stringent so need to meet these requirements.
	Internally Powered Circuits (Battery) to Patient Applied Part (Enclosure)	≤15Vdc	Two Levels	MOPP	3.4	12	No	--	1.6	15	1	1.6	1000	No	
	Internally Powered Circuits (Battery) to Patient Applied Part (Enclosure)	≤15Vdc	Two Levels	MOPP	3.4	12	No	--	1.6	12	1	1.6	1000	No	

Assumptions Used:
CC outside patient environment
HHC inside the patient environment
Material group unknown so use Material Group IIIb
Pollution degree 2
No accessible metal on CC or HHC
Maximimum elevation for HHC & CC ≤ 2000m

CC Specs
Charger circuit Vmax = 18V
Battery Pack Vmax = 12.6V Vmin = 9.9
The CC has only one block and that is the Dual Charging circuit. Vin = 15V Vout (x2) = 12.6V

HHC Specs
Battery Pack Vmax = 12.6V Vmin = 9.9
Max Ciruiutry Voltage = 36V

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Step 5

Fig 5 of IEC 60601-1
Schematic flow chart for component qualification (Cl. 4.8

Step 5 – Critical Components Qualification

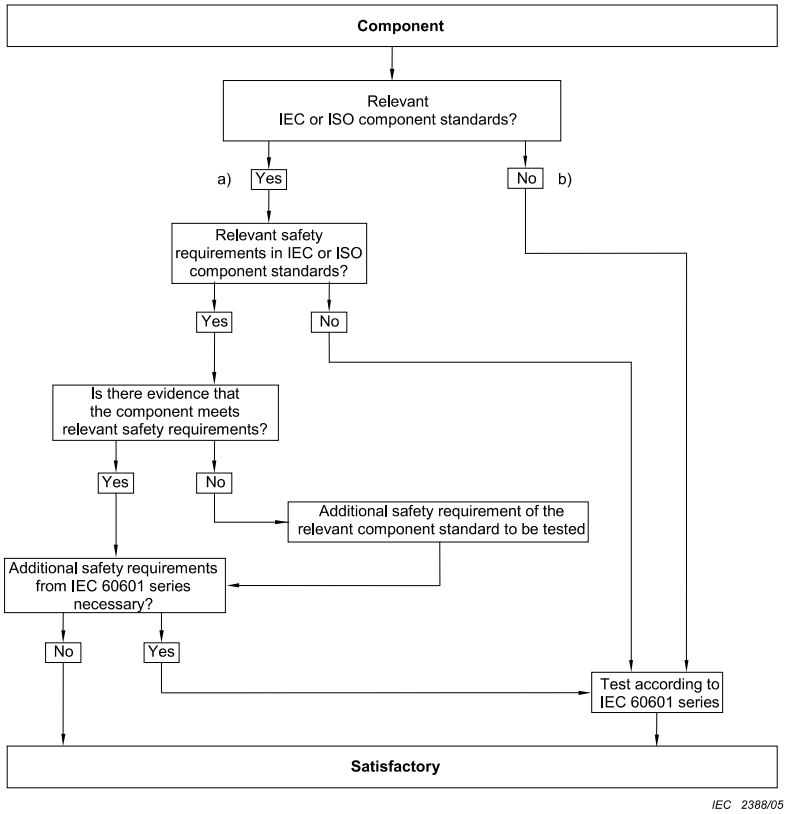

Figure 5 – Schematic flow chart for component qualification
(see 4.8)

Step 8

1) Change to Blue Man Symbol – Corrigendum 1
When Mandatory Action Required as a Risk Control Measure
2) Annex C Examples

Step 8 – Labelling & Marking Requirements

- Corrigendum 1 - December 2006
  - Modified 7.2.3, 8.2.2 & Table D.2, item 10

Instead of:

10		IEC 60878 Safety 01 [b]	Follow operating instructions NOTE On ME EQUIPMENT "Follow instructions for use"

read:

10		ISO 7010-M002	Refer to instruction manual/ booklet NOTE On ME EQUIPMENT "Follow instructions for use"

Delete table footnote [b].

Step 8 – Labelling & Marking Requirements

Annex C Summary of Tables

- Table C1 - External Markings
- Tables C2 - Internal Markings
- Table C3 - Controls & Instruments
- Table C4 - Accompanying Documents - General section
- Table C5 – IFU
- Table C6 - Technical Description

Step 8 – Labelling & Marking Requirements

Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use

Description of requirement	Subclause
ACCESSIBLE PARTS: instruction not to touch them and the PATIENT simultaneously	8.4.2 c)
ACCESSIBLE PARTS: instructions to the OPERATOR to open ACCCESS COVERS	8.4.2 c)
APPLIED PARTS (hot or cold): temperatures and clinical effects of	11.1.2.1
APPLIED PARTS not intended to deliver heat: temperature exceeding 41 °C	11.1.2.2
Cleaning or disinfection PROCESSES: specification of	11.6.6
Foot-operated controls: intended for use in areas where liquids are likely to be found	15.4.7.3 b)
Mass of ACCESSORIES	9.8.3.2
ME SYSTEMS: other equipment intended to provide power to ME EQUIPMENT	16.3
MOBILE ME EQUIPMENT: requirement that more than one person is needed to move	9.4.2.4 a)
Moving parts: warning of	9.2.1
POTENTIAL EQUALIZATION CONDUCTOR terminal: information on the function and use of	8.6.7
Reservoir or liquid storage chamber: information on overflow HAZARD	11.6.2
Transport conditions: warning for	9.4.2.2

Step 8 – Labelling & Marking Requirements

Table C.6 – ACCOMPANYING DOCUMENTS, technical description

Description of requirement	Clause
CLASS II ME EQUIPMENT with isolated internal screens: explanation of	8.6.9
External means of isolation: description of	8.11.1 b)
Non-automatic discharging device for internal capacitors: specification of	8.4.4
Network requirements for PEMS intended to be connected to an outside network	14.13