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IEC 60601-1:2005/A1:2012 – Overview, Highlights, and Complete List of Changes

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Overview

Amendment 1 to IEC 60601-1:2005 was released in July last year and is now starting to get some attention. It is already acceptable to use the standard in some markets, and many designers and test labs may need to be aware of the changes and also may use the changes to justify alternate solutions.

The basic statistics are:

- 118 pages (English)
- 67 pages of normative text
- ~260 changes
- 21 new requirements
- 63 modifications to requirements or tests
- 47 cases where risk management was deleted or made optional
- 19 corrections to requirements or test methods
- Remainder were reference updates, notes, editorial points or clarifications
- USD$310 for amendment only
- USD $810 for the consolidated edition (3.1)

This document covers some of the highlights, including an in-depth look at essential performance, and is then followed by a complete list of changes with a

Highlights

Risk management has been tuned up and toned down: the general Clause 4.2 tries to makes it clear that for IEC 60601-1, the use of ISO 14971 is really about the specific technical issues, such as providing technical criteria for a specific test or justifying an alternate solution. Full assessment of ISO 14971 is not required, and post market area is specifically excluded. The standard also clearly states that an audit is not required to determine compliance.

Within the standard, the number of references to risk management have been reduced, with some cases of simply reverting back to the original 2nd edition requirements.

Essential performance has quietly undergone some massive changes, but to understand the impact of the changes you need to look at several aspects together, and some lengthy discussion is warranted.

First, the standard requires that **performance limits** must be declared. In the past a manufacturer might just say “blood pump speed” is essential performance, but under Ed 3.1 a specification is also required e.g. “blood pump speed, range 50-600mL/min, accuracy ±10% or ±10mL of setting, averaged over 2 minutes, with arterial pressure ±150mmHg, venous pressure -100~+400mmHg, fluid temperature 30-45℃”.

Next, the manufacturer should consider separately **essential performance in abnormal or fault conditions**. For example under a hardware fault condition a blood pump may not be expected to provide flow with 10% accuracy, but it should still confidently stop the blood flow and generate a high priority alarm. Care is needed, as the definition of a single fault condition includes abnormal conditions, and many of these conditions occur at higher frequency than faults and therefore and require a special response. User errors, low batteries, power failure, use outside of specified ranges are all examples where special responses and risk controls may be required that are different to genuine fault condition. For example, even a low risk diagnostic device is expected to stop displaying measurements if the measurement is outside of the rated range or battery is too low for accurate measurement. Such responses are now also considered “essential performance”.

Essential performance must also be **declared in the technical description**. This is major change since it forces manufactures to declare essential performance in the commercial world, especially visible since most manufacturers incorporate the technical description in the operation manual. Until now, some manufacturers have declared there is no essential performance, to avoid requirements such as PEMS. But writing “this equipment has no essential performance” would raise the obvious question … what good is the equipment?

Finally many of the tests which previously focused on basic safety now include **essential performance** in the **test criteria**. In edition 3.0 of the general standards, the only test clause which required essential performance was the defibrillator proof tests. Now, essential performance is mentioned in the compliance criteria many times in Clauses 9, 11 and 15. These are stress tests including mechanical tests, spillage, sterilization and cleaning. The good news is that the standard makes it clear that **functional tests** are only applied if necessary. So if engineering judgment says that a particular test is unlikely to affect performance, there is no need to actually test performance.

While essential performance is dramatically improved there are still two areas the standard is weak on. First, is there is no general clause which requires a base line of essential performance to be established. Typically, performance is first verified in detail under fairly narrow reference conditions (e.g. nominal mains supply, room 23±2℃, 40-60%RH, no particular stress conditions). Once this base line is established, performance is then re-considered under a range of stress conditions representing normal use (±10% supply voltage, room temperature 10-40℃, IP tests, mechanical tests, cleaning test, and so on). Since there are many stress tests, we normally use engineering judgment to select which items of performance, if any, need to be re-checked, and also the extent of testing. But this selective approach relies on performance having been first established in the base-line reference condition, something which is currently missing from the general standard.

The second problem is the reference to essential performance in PEMS (Clause 14). Many low risk devices now have particular standards with essential performance. And since essential performance is used as a criteria for stress tests, the “no essential performance” approach is no longer reasonable. But the application of complex design controls for lower risk devices is also unreasonable, and conflicts with modern regulations. Under note 2, the committee implies that Clause 14 needs only to be applied to *risk controls*. A further clarification would be to refer to risk controls that *respond to abnormal conditions*. For example, in a low risk device, the low battery function might be subject to Clause 14, but the main measurement function should be excluded, even if considered “essential performance”. It would be great if the committee could work out a way to ensure consistent and reasonable application for this Clause.

Moving away from essential performance to other (more briefly discussed) highlights are:

- Equipment **marking** requirements: **contact information, serial number** and **date of manufacture** are now required on the labeling, aligning with EU requirements. The serial number is of special note, since the marking method is often different to the main label.

- **Accessories** are also required to marked with the same details (contact information, serial number, date of manufacturer). This also fits with EU requirements, provided that the accessory is placed on the market as a separate medical device. This may yield an effective differentiation between an "accessory" and a "detachable part" – accessories are detachable parts which are placed on the market separately.

- Both the **instructions for use** and the **technical description** must have a **unique identifier** (e.g. revision number, date of issue)

- For **defibrillator tests**, any unused connectors must not allow access to defibrillator energy (effectively requires isolation between different parts, or special connectors)

- Mechanical tests for **instability** and **mobile** equipment (rough handling test) are modified (market feedback that found the tests to be impractical)

- The previous 15W/900J exemption of secondary circuits from fire enclosure/fault testing has been expanded to 100VA/6000J if some special criteria are met (e.g. using PCB with FV1 rating). Since the criteria are easy to meet, it will greatly expand the areas of the equipment that does not need a fire enclosure or flame proof wiring; welcome news considering the huge environmental impact of flame retardants.

- For PEMS, selected references to IEC 62304 are now mandatory (Clauses 4.3, 5, 7, 8 and 9)

Complete List of changes in IEC 60601-1:2005, Amendment 1:2012

The following table shows each of the changes with brief description and category such as new, modified, clarified or corrected:

Clause	Subject	Category	Change
3	Definitions		• 43 definitions modified • 8 new definitions • Most are to update to current standards (e.g. update to ISO 14971:2007 terms) • Many just modify the note (not definition • Only significant definitions mentioned below
3.27	Definition: Essential performance	Modified	• Performance of a "clinical function" • Not basic safety • Loss beyond limits

3.28	Definition: Expected service life	Modified	• Period which basic safety and essential performance is maintained
3.141 ~ 3.143	Definition: Alarm condition, signal, system	New	• Definition of alarms, from IEC 60601-1-8 (including amendment 1:2012)
3.144	Definition: Body worn	New	• Covers equipment worn by the patient
4.2	Risk management	Modified	• Substantially expanded • Update to ISO 14971:2007 edition • Exclude post market actions
4.3	Essential performance	Modified	• Substantially updated • Separate for normal condition, single fault condition • Specific performance limits required • Functional tests to establish essential performance are only required only where necessary (assess for each test)
4.5	Alternate risk control (equivalent safety)	Modified	• Reworded • Risk “equal to or less” changed to “comparable”
4.6	Non-applied parts	Clarified	• No significant impact
4.11	Power input test	Clarified	• No significant impact
5.1	Type tests	Clarified	• No significant impact
5.4 a)	Other conditions	Clarified	• Least favorable conditions to be documented for every test
5.5 a)	Supply voltage	Clarified	• No significant impact
5.5 c)	Supply voltage	Clarified	• No significant impact
5.7	Humidity test (93% RH)	Deleted RM	• Reverted to the old requirement (48hrs for IPX0, 168hrs for other equipment).
5.9.2.2	Test hook	Clarified	• No significant impact (add dimensional tolerance)
5.9.2.3	Actuating mechanism	Deleted RM	• Revert to old requirement (decision based on if a tool is required)
7.1.1	Usability (IFU)	Deleted	• Simply refer to Clause 12.1
7.1.2	Legibility test	Clarified	• More details on the observer
7.1.3	Durability test	Modified	• “methylated spirit” replaced with “ethanol 96%”
7.2.1	Marking, sterile	Corrected	• Add “single use only” to the items which can be marked
7.2.2	Marking, identification	Added	• New marking required for the equipment: ○ Contact information ○ Serial number ○ Date of manufacture (match with to EU regulation)

7.2.4	Marking, accessories	Added	• New marking required for the equipment: ○ Contact information ○ Serial number ○ Date of manufacture (match with to EU regulation)
7.2.5	Marking, external power supply	Modified Deleted RM	• If external power supply (ac/dc adaptor) is used, one of the following options: ○ Marking of model/type ○ Symbol D.2 No. 10 (link to IFU) ○ Special connector
7.2.6	Marking, rated voltage	Corrected	• No significant impact
7.2.7	Marking, rated input	Clarified	• No significant impact
7.2.10	Marking, applied part	Reference updated	• No significant impact
7.2.14	Marking, HV terminals	Reference updated	• No significant impact
7.2.17	Marking, protective packaging	Reference updated	• No significant impact
	Marking, sterile	Added	• Type of sterilization to be marked
7.2.18	Marking, external pressure source	Added	• Flow rate to be marked
7.2.19	Marking, functional earth	Reference updated	• No significant impact
7.2.21	Mass of mobile equipment	Added	• Mass to be marked (including any load)
7.3.2	Internal marking, HV parts	Reference updated	• No significant impact
7.3.4	Internal marking, fuses	Clarified	• No significant impact
7.3.5	Internal marking, PE terminal	Reference updated	• No significant impact
7.3.6	Internal marking, FE terminal	Reference updated	• No significant impact
7.3.7	Internal marking, supply terminals	Correct RM terminology	• No significant impact
7.4.1	Marking, power switches	Reference updated	• No significant impact
7.4.3	Marking, control devices	Reference updated	• No significant impact
	Marking, control devices	Added	• Optionally allow use of standby symbol
7.4.3	Marking, units of measure	Reference updated	• No significant impact

7.5	Marking, safety signs	Modified	• Symbol D.2.2 (triangle with exclamation) is not required if safety sign has established meaning • Supplementary text (if used) must be in a language suitable for the intended operator
7.6.3	Marking, symbols	Corrected	• No significant impact
7.7.3	Color of insulation	Note updated	• No significant impact
7.9.1	Accompanying documents	Modified	• “address” changed to “contact information”
		Modified	• If manual is provided electronically, decision on what to include is based on usability engineering rather than risk management (IEC 60601-1-6, not ISO 14971)
7.9.2.1	Instructions for use (IFU), general	Added	• Identify parts to be serviced while in use with a patient • New details if patient is the operator
		Added	• Identify name/trade mark, address of manufacturer, and model number
7.9.2.7	IFU, isolation from mains	Clarified	• No significant impact
7.9.2.14	IFU, supplementary equipment	Corrected	• No significant impact
7.9.2.15	IFU, environmental	Deleted RM	• No significant impact
7.9.2.17	IFU, radiation	New	• Disclosure of details of radiation (for medical purpose)
7.9.2.18	IFU, sterile equipment or accessory	New	• Indication of sterile, method of sterilization • Instructions to prevent damage
7.9.2.19	IFU, version identifier	New	• Unique version identifier required (e.g. date or revision number)
7.9.3.1	Technical description	New	• Must include essential performance identified in Clause 4.3 • Unique identifier (e.g. date or revision number)
8.1	Electric shock, fundamentals	Deleted RM	• Remove references to risk
8.2.2	Connection to DC	Deleted RM	• Concept is same. Equipment shall continue to provide essential performance (change from unacceptable risk).
8.3 a)	Type CF applied parts	Note added	• No significant impact
8.4.2	Limitation of	Corrected	• No significant impact (by definition,

(title, b)	voltage, energy		applied parts are not included in accessible parts, thus the title and item b) needed to be corrected)
8.4.2 c)	Exclusion for parts up to 60Vdc etc	Corrected	• "up to 2V" corrected to "more than 2V"
		Deleted RM	• Deletes the reference to the risk management file in the compliance statement
8.4.2 d)	Test rod	Clarified	• No significant impact (dimensional tolerance added)
8.4.3	Shock from pins	Clarified	• No significant impact (clarifies type of equipment that can be used for the test)
8.4.4	Internal capacitive circuits	Reference updated	• No significant impact
8.5.1.1	Means of protection	Reference updated	• No significant impact
8.5.1.2	Means of patient protection	Corrected	• Y2 capacitor allowed as 1 MOPP (should have originally been allowed)
		Added	• Y1 capacitor allowed as 2 MOPP if working voltage is less than 42.4Vpeak ac or 60Vdc
8.5.1.3	Means of operator protection	Corrected	• Y2 capacitors allowed as 1 MOPP (should have originally been allowed)
8.5.1	Compliance statement	Corrected	• Added applied parts (missing)
8.5.2.3	Patient leads and cables	Clarified	• No significant impact (Add the term "cable" as well as lead)
8.5.5.1	Defibrillator protection, operator shock	Modified	• All unused connectors must be protected, even if considered part of the same "applied part" (previously considered under risk management)
8.5.5.2	Defibrillator protection, energy reduction test	Modified	• No need to monitor for energy to other parts during this test (new Figure 11)
8.6.4	Earthing, impedance test	New	• For equipment with an appliance inlet, test with detachable cord is <0.2Ω. If the cord is not supplied or specified, use a 3m cord.
		Modified	• Allows DC to be used for the test
8.6.7	PE conductor	Deleted RM	• Revert to 2nd edition requirement
8.7.1	Leakage current, general	New	• Test must be performed after sterilization (if applicable)
8.7.3	Leakage current, allowable values	Note added	• Note to explain that earth leakage becomes touch current when the earth is opened (common misunderstanding

			in testing)
8.7.3 f)	Leakage current, functional earth	New	• New limits for functional earth (5mA NC, 10mA SFC). Note: although these appear high, new test in 8.7.4.5 a) below still requires touch current to meet 0.1mA NC, 0.5mA SFC limits).
8.7.3	Leakage current, Figure 12	Corrected	• No significant impact (correct “amplitude” to “magnitude”, due to the use of a log scale) “
8.7.4.1	Leakage current, measurements	Modified	• Limit the hazardous situations to those in Clause 13.2 only
8.7.4	Leakage current, Figures	Modified Corrected	• Small corrections and modifications, significant items are: ○ Figure 14, 17, 18: resistance R added to external mains (to limit current in case of fault) ○ Figure 15, 16: Metal plate added under equipment
8.7.4.5 a)	Leakage current, Class II with functional earth	New	• Class II equipment with functional earth tested as if it were Class I equipment
8.7.4.7	Leakage current, patient	Modified	• Separate out Type B and BF: ○ Type B tested all together ○ Type BF, each function tested separately • Add “cables” (instead of just “leads”)
8.8.1	Insulation, general	Clarified	• No significant impact (text is deleted, but covered elsewhere)
8.8.3	Dielectric strength	Note added	• Additional notes, referring to Annex J and 8.8.3 rationale (both of which are informative)
8.8.4.1	Insulation other than on wire	Deleted RM	• Reference to RM is now option (if necessary)
8.9.1.1 ~ 8.9.1.6	Creepage / clearance, part before fuse	Modified	• Table 11 is now deleted, for the part before the mains fuse the limits of Table 13, 14 and 16 are used. This effectively means a change from 3.0mm / 1.6mm to 2.5mm / 2.0mm for cr/cl (assumes 240Vac, PD II, CTI IIIb)
8.9.1.5	Equipment for high altitude	Reference updated	• No significant impact
8.9.1	Spacing for MOOP	Modified	• New values for 25V are added
8.9.2	Spacing, application	Deleted RM	• “hazardous situation” limited to the hazardous situations identified in Clause 13.1
8.9.4	Spacing, rules for measurement	Modified	• The minimum gap of 1mm for groves is now modified according to several factors. However, it remains 1mm for

			most situations.
8.10.2	Fixing of wiring	Deleted RM	• "hazardous situation" limited to the hazardous situations identified in Clause 13.1 (no need to refer to the RMF)
8.10.4.2	Control devices (foot/hand operated), connection cords	Deleted RM	• "hazardous situation" limited to the hazardous situations identified in Clause 13.1
8.10.5	Mechanical connection of wiring	Deleted RM	• "hazardous situation" limited to the hazardous situations identified in Clause 13.1
8.11.1 a)	Isolation device (permanently installed)	New	• Locking means may be required for the isolation device
8.11.1 e)	Isolation device, mains switch	Modified	• Switch now needs to comply with all aspects of IEC 60447 (not just direction of movement)
8.11.1 f)	Isolation device, use of plug	Modified	• Add the phrase "that has no mains switch". Meaning is unclear, but expected to be no significant change
8.11.5	Mains fuses and overcurrent releases	Clarified	• No significant effect (highlight effect of faults in other circuits when eliminating a fuse, rare case)
		Deleted RM	• No longer required to document this in RMF (just "manufacturer's documentation"
8.11.6	Internal wiring of mains part	Clarified	• No significant impact (add phrase "or the appliance inlet", which was already assumed in practice)
9.2.1	Moving parts, general	Correct RM terminology	• Change to "risk controls", also paragraph on residual risk
9.2.2.1	Trapping zone	Correct RM terminology	• Change to "risk controls"
9.2.2.3	Safe distances (Table 20)	Reference update	• No significant impact
9.2.2.4.1	Access to trapping zones	Correct RM terminology	• Change to "risk controls"
9.2.2.4.3	Moveable guards	Deleted RM	• Deleted reference to RMF
9.2.2.4.4	Other risk control measures	Correct RM terminology	• Complete re-work, but concept of clause is same
9.2.2.5	Continuous activation	Correct RM terminology	• concept of clause is same
9.2.2.6	Speed of movement	Correct RM terminology	• concept of clause is same
9.2.3.1	Moving parts, controls	Modified	• Change from RM to usability

9.2.3.2	Overtravel end stops	Deleted RM	• Change from RM to fixed test (Table 33), similar to UL 60601-1:2003 end stop test
9.2.4	Emergency stopping device	Modified	• RM terminology corrected, references updated • Compliance now requires functional tests (previously only inspection of equipment and RMF)
9.2.5	Release of patient	Modified	• RM terminology corrected • Compliance now requires functional tests
9.3	Mechanical hazard from sharp edges	Deleted RM	• Compliance now based on inspection
9.4.1	Instability, general	Deleted RM	• Now simply required to be stable without unexpected movement
9.4.2.2	Instability, excluding transport position	Corrected	• No change in technical content
9.4.2.3 a)	Instability from forces, horizontal	Corrected Modified	• Corrected to clearly indicate either use the label or pass the test • Test parameters are changed: force of 15%, not exceeding 150N (previously 25%, 220N)
9.4.2.3 b)	Instability from forces, vertical	Corrected	• Corrected to clearly indicate either use the label or pass the test
9.4.2.4.3	Castors, wheels, movement over a threshold	Modified Deleted RM	• Test modified to 10mm (from 20mm) • Basic safety and essential performance to be maintained (effectively removes the need for special line in the risk management)
9.4.3.1	Instability in transport (mobile)	Deleted RM	• Test is same, removed the need to refer to risk management
9.4.3.2 a)	Instability excluding transport (mobile)	Deleted RM	• Test is same, removed reference to intended modes of use and risk management.
9.4.3.2 b)	Instability excluding transport (mobile	Modified Deleted RM	• Test parameters are changed: force of 15%, not exceeding 150N (previously 25%, 220N) • Removed reference to risk management
9.4.4	Grips, handling devices	Correct RM terminology	• “hazards” changed to “unacceptable risk”
9.6.1	Acoustic energy	Deleted RM	• Need to refer to RM only if required
9.6.2.1	Audible acoustic energy	Corrected	• Editorial points only, no technical change
9.6.2.1	Audible acoustic	Added	• Allows sound level measurement in-situ

e)	energy		
9.7.4	Pressure rating	Deleted RM	• Deleted reference to RMF
9.7.5	Pressure vessels	Clarified	• Added “(e.g. those with no national certification)”
9.7.6	Pressure control device	Deleted RM	• Deleted reference to RMF
9.8.1	Support systems, general	Clarified	• “hazards” clarified as “mechanical hazards”
9.8.2	Support systems, test	Clarified	• No significant change (editorial only)
9.8.3.1	Support, suspension systems, general	Correct RM terminology Modified	• “minimize the risk” to “no unacceptable risk” • Functional test may be required
9.8.3.2 a)	Support, suspension, static forces, foot rest	Deleted RM	• Removes direct references to risk management • Compliance based 5° deflection, and no impact to basic safety and essential performance
9.8.3.2 b)	Support, suspension, static forces, sitting rest	Deleted RM	• Removes direct references to risk management • Compliance based 5° deflection, and no impact to basic safety and essential performance
9.8.3.3	Dynamic forces	Deleted RM	• Removes direct references to risk management • Compliance based on no impact to basic safety and essential performance
9.8.4.1	Mechanical protective devices	Deleted RM	• Removes reference to risk management, replace with inspection, calculations, functional tests
9.8.4.3	Mechanical protective devices, single activation	Corrected Deleted RM	• Correct to add “ISO” • Remove reference to risk management
9.8.5	Systems without mechanical protective devices	Modified	• Add inspection of design documentation to the compliance statement
10.1.1	X-radiation, unintentional	Clarified	• Limit units changed but effectively same
10.1.2	X-radiation, intentional	Deleted RM	• RMF only required if there is no particular or collateral standard • Link to 12.4.5.x
10.3	Microwave radiation	Deleted RM	• RM replaced by specific test
10.4	Lasers	Modified	• Deleted reference to LEDs • Define scope of application (180nm ~ 1mm)

			• Update reference to IEC 60825-1:2007
11.1.2.2	Applied part temperature	Clarified	• Limits apply in normal and SFC (note: already required under 13.1) • Duration of contact also to be disclosed • No test required if justified in the RMF
11.2.2.1 b)	Oxygen rich environment	Corrected	• Compliance statement includes inspection of the equipment (as well as documentation)
11.6.2	Overflow	Modified	• Refers to basic safety, essential performance as well as unacceptable risk • Tilt test reduced from 15° to 10° • Added mobile test (if appropriate)
11.6.3	Spillage	Modified	• Added basic safety, essential performance as criteria
11.6.5	IP testing	Modified	• Added basic safety, essential performance as criteria
11.6.6	Cleaning, disinfection	Modified	• Added basic safety, essential performance as criteria
11.6.7	Sterilization	Modified	• Corrected reference to standards • Added ISO 17665-1 (equipment intended to be re-sterilized)
11.6.8	Compatibility with substances	Modified	• Reference to the use of standards in place of risk management
11.8	Interruption of the power supply	Modified	• Added basic safety, essential performance as criteria
12.2	Usability	Modified	• More direct link to IEC 60601-1-6 (previous was only “see IEC 60601-1-6).
12.3	Alarm systems	Modified, Deleted RM	• More direct link to IEC 60601-1-8, remove reference to risk management (note: there is risk management in IEC 60601-1-8)
12.4.2	Indications relevant to safety	Modified	• Previously “indication of parameters” changed to “indicate and hazardous output”
12.4.5.2	Diagnostic X-ray	Modified, Deleted RM	• More direct link to IEC 60601-1-3, remove reference to risk management
13.1.2	Defined hazardous situations	Corrected, modified	• Editorial point in 6th dash (“or” to “of”) • New exclusion for secondary circuits from SFC testing (if FV1, <100VA, 6000J, wire of certain types) *→ this exclusion will allow some secondary circuits to avoid needing a fire enclosure* • Exclusion of high integrity components (obviously intended, but not stated before)

13.2.7	Impairment of cooling	Title only	• Correct RM terminology
13.2.13.1	Overload test, conditions	Modified	• "approximately room temperature" changed to "within 3°C of room temperature"
14.1	PEMS, general	Modified	• Rewording, but effectively same • Note 2 states that if a risk control is implemented within a PEMS, the clause must be applied *→ the inference is that PEMS is really intended for risk controls* • Selected requirements from IEC 62304 are now mandatory (Clauses 4.3, 5, 7, 8 and 9)
14.2	Documentation	Modified	• Appears to allow PEMS documentation to be kept outside of the risk management file
14.6	Known and foreseeable hazards	Modified	• Modified text relating to IT-networks
14.6.2	Risk control	Update reference	• Correct reference to ISO 14971
14.8	Architecture	Modified	• Reference to IT-Network
14.9	Design and implementation	Modified	• Deleted reference to risk management file (but design environment still needs to be documented)
14.11	PEMS validation	Modified	• Deleted checks for unintended functioning
14.12	Modified	Added	• For software, Clauses 4.3, 5, 7 and 8 to be followed when software is modified
14.13	PEMS, IT-Network	Modified	• Re-worded, similar in content with addition warnings to the responsible organization
15.1	Arrangement of controls, indicators	Modified	• Change from risk management to usability, direct link to IEC 60601-1-6
15.3.1	Mechanical strength, general	Deleted RM Modified	• Unacceptable risk changed to loss of basic safety or essential performance • Table 28 expanded to include body worn equipment
15.3.2	Push test	Deleted RM	• Deleted reference to RMF (criteria is now loss of basic safety or essential performance)
15.3.3	Impact test	Deleted RM	• Deleted reference to RMF (criteria is now loss of basic safety or essential performance)
15.3.4.1	Drop test, hand held	Modified Deleted RM	• Added accessories • Deleted reference to RMF (criteria is now loss of basic safety or essential performance)

15.3.4.2	Portable ME equipment	Modified Deleted RM	• Added accessories • Deleted reference to RMF (criteria is now loss of basic safety or essential performance)
15.3.5	Rough handling test	Modified Deleted RM	• Added precautions in test • Increase test speed to 0.8m/s (from 0.4m/s) • Deleted reference to RMF
15.4.1	Construction of connectors	Deleted RM	• RMF only required if connectors are interchangeable
15.4.2.1	Temperature and overload devices	Correct RM terminology Updated reference	• Not expected to produce any significant change
15.4.3.1	Batteries, housing	Correct RM terminology, Deleted RM	• RMF only required “where appropriate”
15.4.3.4	Lithium batteries	Modified	• Correct standards are listed for both primary and secondary lithium batteries (IEC 60086-4, IEC 62133 respectively) • Reference to hazard remove (mandatory for all lithium batteries and cells)
15.4.3.5	Batteries, Excessive current	Modified Deleted RM	• Justification for omission just needs to be document, not in the RMF • New paragraph indicating means of protection can be used if 2 MOOP provided • Remove reference to RMF in compliance
15.4.6.1	Fixing of controls	Modified Deleted RM	• Remove reference to RMF (test is always required)
15.4.6.2	Limitation of movement	Deleted RM	• Deleted reference to hazardous situation (“where necessary” remains)
15.4.7.3	Entry of liquids	Deleted RM	• Deleted reference to RMF, IPX6 is based on location of use
15.5.1.1	Transformers, protective components	Modified	• Only components with 2 MOOP or high integrity components can remain in circuit (otherwise, the short or overload is applied directly to the transformer terminals)
15.5.1.2	Short circuit test	Corrected	• Refers to both the 5X and 2X test (previously incorrectly referred to the 5X test only, which meant theoretically even SMPS transformers needed the 2X test, which is not practical)
15.5.1.3	Overload test	Clarified	• Overload test may be applied after rectification (as is normally done)
15.5.2	Dielectric strength	Modified	• Transformers above 1kHz are excluded from the test

15.5.3	Construction of transformers	Modified	• Reference to IEC 61558-1 removed • Old requirements from 2nd edition used
16.3	Systems, Power supply	Added	• New requirement for equipment receiving power from isolated power supply or UPS; restricting transients to within specifications of the supply; or declare if the supply is not specified
16.6.4.1	System, Leakage current, measurements	Modified	• No significant impact (added “total patient leakage current”)
16.8	Systems, Power supply interruption	Deleted RM	• Criteria changed to basic safety / essential performance from “unacceptable risk”
16.9.1	Systems, Connections	Modified	• Clause made same as 15.4.1, including addition of gas connectors
16.9.2.1 c)	Systems, Earthing	Modified	• Previously 400mΩ allowed, now reverted to limits in 8.6 (200mΩ)
16.9.2.1 d)	Systems, isolating transformers	Modified	• Transformers complying with IEC 60601-1:2005 also allowed (as is common practice)
16.9.2.2	Systems, protective earth connections	Added	• New paragraph, re-confirms limit of 200mΩ