Figure A.25 – Example of Scenario 2

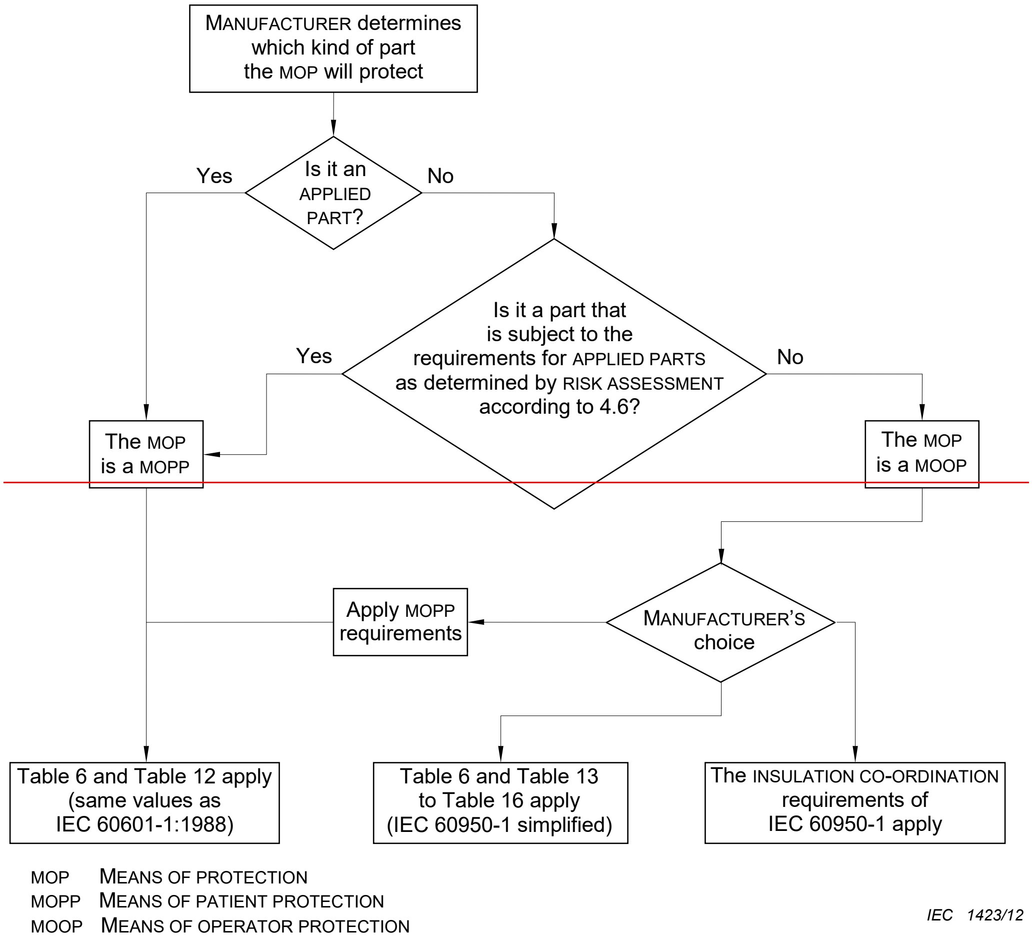
The analysis focused on these scenarios. The purpose was to determine if any differences in the application of requirements of IEC 62368-1:2018 would be necessary based on the use scenario.

Where IEC 62368-1:2018 has been identified as an acceptable alternative to the requirements of this standard or IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013, no additional rationale has been written.

During the review process, some differences in terminology were identified between this standard and IEC 62368-1:2018. Specifically, the definitions for TOUCH CURRENT and PEAK WORKING VOLTAGE were reviewed; while differences were noted, it was determined that these differences did not have any technical effect on the use of IEC 62368-1:2018 as identified in the body of this document.

Y capacitors are used to reduce radio frequency interference by providing a low impedance path to earth for high frequency a.c. They are also used for bridging DOUBLE or REINFORCED INSULATION as part of the interference suppression regime. There are four types: Y1, Y2, Y3 and Y4. Y1 capacitors are designed for use with three phase mains and have a WORKING VOLTAGE of up to 500 V a.c. and a withstand voltage of 4 000 V a.c. Y2 capacitors are designed for use with single phase mains and have a WORKING VOLTAGE up to 300 V a.c. and a withstand voltage of ~~2 500~~ 1 500 V a.c. Y3 capacitors are similar to Y2 capacitors but have a WORKING VOLTAGE up to 250 V a.c. Y4 capacitors are designed for use with low voltage mainsand have a WORKING VOLTAGE up to 150 V a.c. and a withstand voltage of 1 000 V a.c. These capacitors are safety critical since they provide a leakage path to earth or across a barrier. So they must be certified and monitored by a recognised test house to IEC 60384-14, which serves to control their manufacture.

~~One Y1 capacitor can be used to provide two MOOP's but only one MOPP (PATIENTS need a higher level of protection than OPERATORS). A Y2 capacitor can be used to provide one MOOP only.~~



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

Subclause 8.5.1.2 – MEANS OF PATIENT PROTECTION (MOPP)

CREEPAGE DISTANCES:

A detailed review of the requirements for CREEPAGE DISTANCES from IEC 62368-1:2018, IEC 60950-1:2005 and this standard confirmed that there were no significant changes in the requirements and that 2 MOOP according to IEC 62368-1:2018 will provide 1 MOPP according to this document.

When determining creepage distances according to IEC 62368-1:2018, the largest value from IEC 62368-1:2018, Table 17 or Table 18 is always applied. This is clarified in the text at the bottom of IEC 62368-1:2018, Table 17.

AIR CLEARANCE:

Table 13 and Table 14 were reviewed to determine where barriers providing 2 MOOP would also satisfy the requirements for 1 MOPP from Table 12. Based on historical discussions, it has been assumed that 2 MOOP would always also meet the requirements for 1 MOPP with respect to AIR CLEARANCE requirements; however, limitations were identified which led to the addition of NOTE 4 in Table 12.

IEC 60950-1:2005, Table 2K and Table 2L and IEC 62368-1:2018, Table 10 to Table 15 (inclusive) were evaluated for the same purpose and compared to Table 12.

This review of the requirements for AIR CLEARANCE between Table 12, IEC 60950-1:2005, Table 2K and Table 2L and IEC 62368-1:2018, Table 10 to Table 14 (inclusive) identified limitations for when 2 MOOP would provide 1 MOPP. This is important when evaluating separation from the SUPPLY MAINS (typically provided by a switch mode power supply or similar component) since a barrier providing 2 MOOP will not always provide 1 MOPP as currently required by this document. Additional information and examples are provided below.

Table 13 is copied from IEC 60950-1:2005, Table 2K; Table 14 is copied from IEC 60950-1:2005, Table 2L.

The values documented in IEC 62368-1:2018 are based on the approach for AIR CLEARANCE values as specified in the basic safety publication IEC 60664-1. The values in this standard are not based on this same approach. Since the scope of Amendment 2 is fixed, a re-evaluation of the current AIR CLEARANCE requirements is not within the scope of this review. It is however expected that this review should be done as part of the fourth edition.

The results of this review identified that the requirements for 2 MOOP according Table 13 and Table 14, or IEC 60950-1:2005, Table 2K and Table 2L will meet the requirements for 1 MOPP according to Table 12 only up to and including a WORKING VOLTAGE of 707 V d.c. / 500 V r.m.s. (Rows 1 to 7 of Table 12).

Examples:

Table 12, Table 13 and Table 14 and IEC 60950-1:2005, Table 2K and Table 2L:

Example 1 (Acceptable): A 240 V r.m.s. mains powered switch mode power supply with a WORKING VOLTAGE of 400 V r.m.s. across the switching barrier would require 3,5 mm AIR CLEARANCE for 1 MOPP according to Row 6 of Table 12. Assumptions: Overvoltage Category II, Pollution degree 2, Altitude 2 000 m.

The requirement for 2 MOOP from Table 13 would be 4,0 mm (Row 2, based voltage of 340 V peak / 240 V r.m.s., based on the RATED MAINS VOLTAGE, see 8.9.1.10) plus 0,4 mm from Table 14 (PEAK WORKING VOLTAGE, which would be a minimum of 566 V peak; Row 3) equal to 4,4 mm AIR CLEARANCE total. Assumptions: Overvoltage Category II, Pollution degree 1, 2 and 3, Altitude 2 000 m.

In this example, the minimum AIR CLEARANCE would not be less than 4,4 mm which meets the requirement of 2,5 mm from Row 6 of Table 12.

Example 2 (Unacceptable): A 240 V r.m.s. mains powered switch mode power supply with a WORKING VOLTAGE of 401 V r.m.s. across the switching barrier would require 4,5 mm AIR CLEARANCE for 1 MOPP according to Row 7 of Table 12. Assumptions: Overvoltage Category II, Pollution degree 2, Altitude 2 000 m.

The requirement for 2 MOOP from Table 13 would be 4,0 mm (Row 2, based voltage of 340 V peak / 240 V r.m.s., based on the RATED MAINS VOLTAGE, see 8.9.1.10) plus 0,4 mm from Table 14 (PEAK WORKING VOLTAGE, which would be a minimum of 567 V peak; Row 3) equal to 4,4 mm AIR CLEARANCE TOTAL. Assumptions: Overvoltage Category II, Pollution degree 1, 2 and 3, Altitude 2 000 m.

In this example, the minimum AIR CLEARANCE could be 4,4 mm which does not meet the requirement of 4,5 mm from Row 7 of Table 12.

A comparison between Table 12 and IEC 62368-1:2018, Table 10 to Table 14 (inclusive) was also performed. This comparison determined that DOUBLE INSULATION or REINFORCED INSULATION according to IEC 62368-1:2018 (which is equivalent to 2 MOOP) will meet the requirements for 1 MOPP according to Table 12 only up to and including 354 V d.c. / 250 V r.m.s.

Table 12 and IEC 62368-1:2018, Table 10 to Table 14 (inclusive):

Example 3 (Acceptable): A 240 V r.m.s. mains powered switch mode power supply with a WORKING VOLTAGE of 250 V r.m.s. across the switching barrier would require 2,5 mm AIR CLEARANCE for 1 MOPP according to Row 5 of Table 12. Assumptions: Overvoltage Category II, Pollution degree 2, Altitude 2 000 m.

The requirement for REINFORCED INSULATION (2 MOOP) from IEC 62368-1:2018 is taken as the higher value of the values determined per Procedure 1 or Procedure 2:

Procedure 1: Assume altitude of 2 000 m (no multiplication factor for AIR CLEARANCES)

- IEC 62368-1:2018, Table 10 would be 2,54 mm (Row 9, based on a temporary overvoltage of 2 000 V); Pollution degree 2
- IEC 62368-1:2018, Table 11 would be 0,14 mm (Row 1, based on peak voltage of 354 V); Pollution degree 2
- Highest value = 2,54 mm

Procedure 2: Assume altitude of 2 000 m (no multiplication factor for AIR CLEARANCES); Pollution degree 2

- IEC 62368-1:2018, Table 14 would be 3,0 mm (Row 10, based on mains transient voltage of 2 500 V)

As an alternative to Procedure 2, the value from Procedure 1 can be used with an additional electric strength test according to IEC 62368-1:2018, Table 15.

In either case the minimum AIR CLEARANCE would not be less than 2,54 mm which meets the requirement of 2,5 mm from Row 5 of Table 12.

Example 4 (Unacceptable): A 240 V r.m.s. mains powered switch mode power supply with a working voltage of 251 V r.m.s. across the switching barrier would require 3,5 mm AIR CLEARANCE for 1 MOPP according to Row 6 of Table 12. The requirement for REINFORCED INSULTATION (2 MOOP) is taken as the higher value of the values determined per IEC 62368-1:2018 Procedure 1 or Procedure 2:

Procedure 1: Assume altitude of 2 000 m (no multiplication factor for AIR CLEARANCES)

- IEC 62368-1:2018, Table 10 would be 2,54 mm (Row 9, based on a temporary overvoltage of 2 000 V); Pollution degree 2
- IEC 62368-1:2018, Table 11 would be 0,14 mm (Row 1, based on peak voltage of 355 V); Pollution degree 2
- Highest value = 2,54 mm

Procedure 2: Assume altitude of 2 000 m (no multiplication factor for AIR CLEARANCES); Pollution degree 2

- IEC 62368-1:2018, Table 14 would be 3,0 mm (Row 10, based on mains transient voltage of 2 500 V)

As an alternative to Procedure 2, the value from Procedure 1 can be used with an additional electric strength test according to IEC 62368-1:2018, Table 15. In this case, the minimum AIR CLEARANCE could be 2,54 mm.

Neither 3,0 mm nor 2,54 mm meet the requirement of 3,5 mm from Row 6 of Table 12.

Additional information on differences between the methods for determining AIR CLEARANCE requirements between this standard, IEC 60950-1:2005 and IEC 62368-1:2018:

A number of differences in the methods for determining the AIR CLEARANCE requirements between the standards evaluated were identified. The method specified in IEC 62368-1:2018 is more complicated than the method used according to this standard and IEC 60950-1:2005. These differences were discussed with experts from IEC TC 108 (technical committee for IEC 60950-1:2005 and IEC 62368-1:2018) to confirm these differences were properly understood by experts from IEC/TC 62. One of the differences is that WORKING VOLTAGE (d.c. or r.m.s.) is used to determine the AIR CLEARANCE requirements according to this standard or IEC 60950-1:2005. IEC 62368-1:2018 instead uses the term “voltage” which can have three different meanings depending on the circuit. “Voltage” can mean either the peak value of the working voltage, the transient overvoltage or the temporary overvoltage–in all cases, the highest value of this “voltage” is used to determine the AIR CLEARANCE requirement.

IEC TC 108 published a Technical Report (IEC TR 62368-2 [77]) which explains the process. The excerpt shown below is intended to provide a basic overview of how AIR CLEARANCE requirements according to IEC 62368-1:2018 are determined.

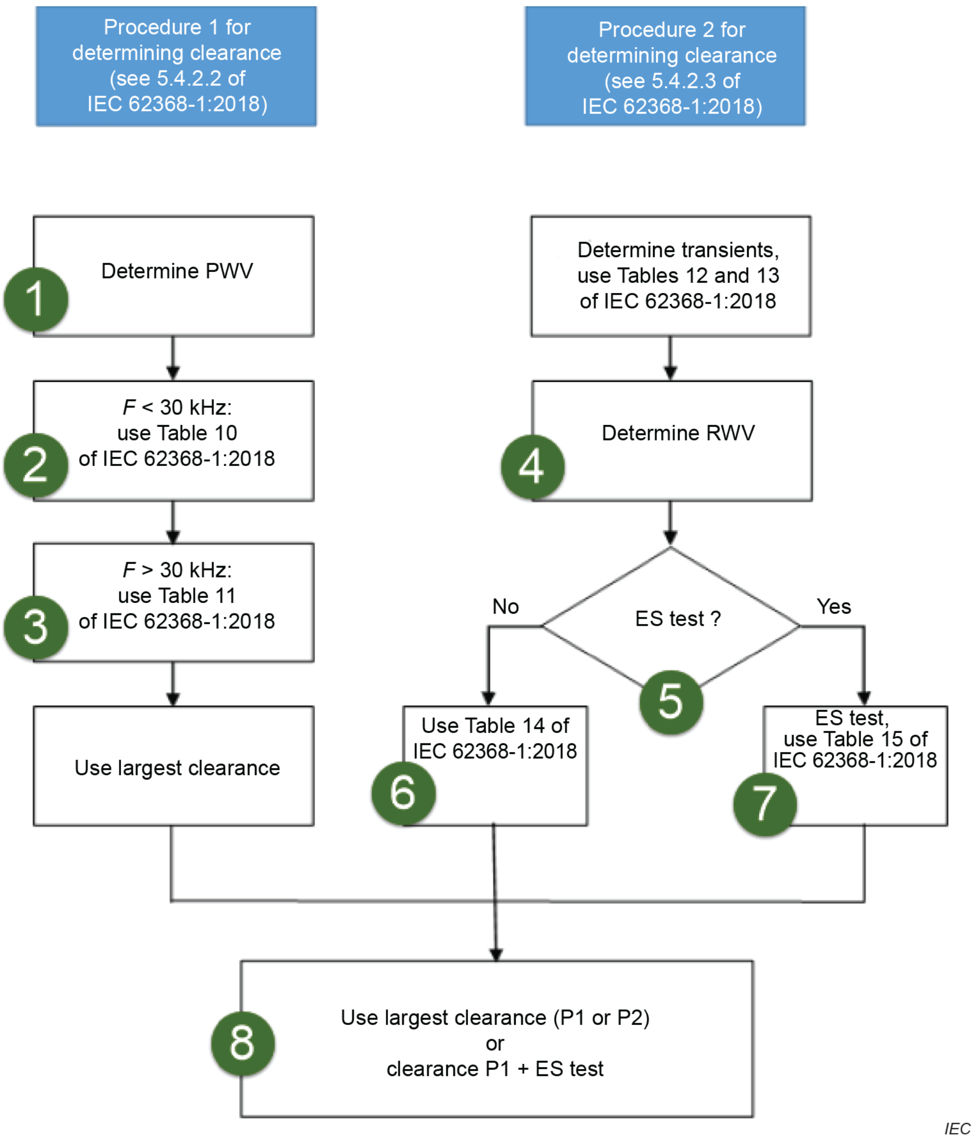


Figure A.26 – Procedure for determination of AIR CLEARANCE requirements IEC TR 62368-2:2019 [77], 5.4.2.1 (modified)

The steps 1-8 identified in Figure A.26 have been added to aid in the explanation below:

Procedure 1 (P1)

Step 1: Determine the peak of the working voltage (PWV)–for a mains connected switch mode power supply, this would be the peak value of the switching voltage, not the peak value of the SUPPLY MAINS voltage.

Step 2: IEC 62368-1:2018, Table 10 is used to determine the required AIR CLEARANCE. For mains connected equipment, this table will always be applicable. When using this table, it is the temporary overvoltage that is used in the voltage column (not the SUPPLY MAINS voltage). IEC 62368-1:2018, 5.4.2.2 specifies a temporary overvoltage of 2 000 V peak to be used if the SUPPLY MAINS voltage does not exceed 250 V (assumed to mean 250 V r.m.s.). For SUPPLY MAINS voltages above 250 V and not exceeding 600 V, the temporary overvoltage is 2 500 V peak. Using this information along with the pollution degree, IEC 62368-1:2018, Table 10 provides a value for the required AIR CLEARANCE.

Step 3: Using the peak of the WORKING VOLTAGE, IEC 62368-1:2018, Table 11 will provide a value for the required AIR CLEARANCE assuming Pollution Degree 2. For pollution degree 1 or pollution degree 3, the multiplication factor specified in the table is used.

The largest value from Step 2 or Step 3 is recorded as the requirement.

Procedure 2 (P2)

Step 4: Determine the required withstand voltage (RWV). The RWV is based on the supply circuit and is either a transient voltage, AC mains transient voltage, DC mains transient voltage or external circuit transient voltage. IEC 62368-1:2018 provides requirements for either determining this voltage based on information about the supply circuit or measuring this voltage. As an example, a SUPPLY MAINS circuit operating at 240 V r.m.s. would use the AC mains transient voltage of 2 500 V peak for an overvoltage category II supply (IEC 62368-1:2018, Table 12).

Step 5: There are 2 methods of satisfying Procedure 2, Method A or Method B:

Method A: Apply IEC 62368-1:2018, Table 14 to determine an AIR CLEARANCE value (Step 6), or

Method B: Apply IEC 62368-1:2018, Table 15 to determine an electric strength test value to be used (Step 7).

Step 6: Take the RWV value determined in Step 4 and determine the required AIR CLEARANCE from IEC 62368-1:2018, Table 14 using the RWV along with the pollution degree. Skip Step 7.

Step 7: Use IEC 62368-1:2018, Table 15 to determine the electric strength test voltage using the RWV determined in Step 4.

Step 8: Determine the required AIR CLEARANCE–this is either the highest value determined using Procedure 1 (Step 3) and Procedure 2 (Step 6) or the value from Procedure 1 (Step 3) with the electric strength test (Step 7).

Subclause 8.5.2.1 – F-TYPE APPLIED PARTS

The essential feature of an F-TYPE APPLIED PART is its separation from other parts. This subclause specifies and quantifies the necessary degree of separation.

Multiple functions can be considered as multiple APPLIED PARTS (which have to be separated from each other by one MEANS OF PATIENT PROTECTION) or as one APPLIED PART. This is decided by the MANUFACTURER after assessing the RISK that earthing of one or more of the

PATIENT CONNECTION(S) of one function could result in excessive LEAKAGE CURRENT through the PATIENT CONNECTION(S) of another function, in the condition in which an unintended voltage originating from an external source becomes connected to the PATIENT.

The 500 V r.m.s. limit for protective devices was already specified in the first edition of this standard. The original rationale is not known, but this voltage corresponds to the highest RATED voltage specified in 4.10.

Subclause 8.5.2.2 – TYPE B APPLIED PARTS

This requirement addresses the possibility that an unintended voltage originating from an external source becomes connected to a part of the ME EQUIPMENT. In the absence of appropriate separation between such a part and PATIENT CONNECTIONS, an excessive PATIENT LEAKAGE CURRENT could result.

According to Clause 17 c) of the second edition of this standard, this requirement applied to all APPLIED PARTS, but in many cases it no longer applies:

– For F-TYPE APPLIED PARTS, the isolation required by 8.5.2.1 also covers this situation (but TYPE BF APPLIED PARTS require an additional test, as explained in the rationale to 8.7.4.7 d)).
– ~~The RISK cannot arise~~ A HAZARDOUS SITUATION cannot develop if either the ME EQUIPMENT part concerned or the PATIENT CONNECTIONS of a TYPE B APPLIED PART are PROTECTIVELY EARTHED. (Failure of the PROTECTIVE EARTH CONNECTION together with the appearance of the unintended voltage would be a double fault condition.)
– If the ME EQUIPMENT part concerned is physically contiguous with the APPLIED PART (for example a dental handpiece) the requirement does not apply if the RISK of contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low.

Subclause 8.5.2.3 – PATIENT leads or PATIENT cables

There are two sets of circumstances to guard against:

– firstly, for TYPE BF APPLIED PARTS and TYPE CF APPLIED PARTS, there should be no possibility of an accidental PATIENT-to-earth connection via any lead that can become detached from the ME EQUIPMENT; even for a TYPE B APPLIED PART an unwanted connection to earth can have an adverse effect on the operation of the ME EQUIPMENT;
– secondly, for all types of APPLIED PART, there should be no possibility of connecting the PATIENT accidentally to parts of ME EQUIPMENT or other conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow.

An extreme case of the latter HAZARD would be a direct connection to the SUPPLY MAINS, resulting from insertion of the connector into a mains outlet or into the socket end of a DETACHABLE POWER SUPPLY CORD. It is essential to prevent this from occurring.

With certain combinations of PATIENT and MAINS CONNECTORS it will be possible to plug the PATIENT connector accidentally into the mains socket.

This possibility cannot reasonably be removed by dimensional requirements as to do so would make single-pole connectors excessively large. Such an incident is rendered safe by the requirement for the PATIENT connector to be protected by insulation having a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of at least 1 500 V. The latter on its own would not suffice as 1 500 V protection could easily be achieved by thin plastic foil that would not stand up to daily wear or to being pushed, possibly repeatedly, into a mains socket. For this reason also it can be seen that the insulation should be durable and rigid.

The wording of this requirement was modified from that in the second edition of this standard to avoid use of the phrases “conductive connection”, which was eliminated as a defined term. This change was a direct result of National Committee comments during the preparation of this edition.

According to the rationale in the second edition of this standard, the test in which the test finger is applied with a force of 10 N was intended "to check the strength of the insulating material." This has now been supplemented by an explicit cross reference to 8.8.4.1.

In response to an enquiry, one National Committee stated that this test is "a mechanical test of the protective cover over the pin;" suggesting that the test was intended to apply specifically to one particular kind of connector design, in which the contact is surrounded by a movable sheath designed to allow contact with the correct mating connector but not with other parts.

During the development of this edition of this standard, the question arose whether this test should be restricted to single-pole connectors, as in the second edition of this standard, or should apply to multi-pole connectors as well. Some multi-pole connectors are of similar shape to single-pole connectors and could similarly be inserted into a MAINS CONNECTOR, so the same considerations of adequacy of insulation apply equally. On the other hand, typical kinds of multi-pole connectors that are in common use cannot be inserted into a MAINS CONNECTOR, but would fail this test if they were subject to it, because the test finger can easily touch their contacts, even without the application of a 10 N force.

A further enquiry to the National Committees yielded a range of responses, with reasonable consensus on some questions but no consensus as to whether this test should apply to all connectors or should be restricted to single-pole connectors.

This test should certainly apply to a multi-pole connector that is of such shape and size that it could be inserted into a mains socket. In this case, the RISK is the same as with a single-pole connector.

Another reason for applying this test to some multi-pole connectors is that the test with the flat plate does not exhaustively assess the possibility of contact with conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow. Almost any kind of connector, if detached from the ME EQUIPMENT or dropped, could possibly make contact with something besides the intended mating connector, but the RISK depends on the shape of the connector and the circumstances. In most cases the RISK is low. For example a typical "D" connector is likely to make contact with an earthed object only momentarily, whereas a straight pin could make contact for a prolonged period. However even prolonged contact with a metal object can result in a ~~HAZARD~~ HAZARDOUS SITUATION only if it occurs in combination with a fault or abnormal situation that allows an excessive current to flow through the PATIENT. The RISK is in all cases much less than the RISK if the connector can make contact with a mains socket. The requirements of this standard should be formulated in relation to the RISK. The standard should minimise RISK to the PATIENT, while allowing MANUFACTURERS a reasonable range of choice of connectors.

"Any connector" should be understood to include multiple contact connectors, several connectors and connectors in series.

The dimension of 100 mm diameter is not in the least important and merely serves to indicate the scale of the flat surface. Any sheet of conductive material larger than this would be suitable.

Subclause 8.5.3 – MAXIMUM MAINS VOLTAGE

Several requirements and tests of this standard relate to the possibility that an unintended voltage originating from an external source becomes connected to the PATIENT or to certain parts of the ME EQUIPMENT. The actual magnitude of such a voltage is unknown; but according to the second edition of this standard it was taken to be the highest RATED MAINS VOLTAGE, or for polyphase equipment the phase to neutral supply voltage. These values reflected a reasonable worst-case assumption that the actual unintended external voltage is unlikely to exceed the voltage of the SUPPLY MAINS in the location where the ME EQUIPMENT is used, and that ME EQUIPMENT is unlikely to be used in a location where the SUPPLY MAINS has a voltage higher than its highest RATED MAINS VOLTAGE. For INTERNALLY POWERED ME EQUIPMENT the value specified ~~was (and remains) 250 V~~ is 240 V, because this is the highest commonly encountered phase-to-neutral voltage in locations where ME EQUIPMENT is used.

In early drafts of this edition, the corresponding wording only referred to a.c. SUPPLY MAINS. This mistake was pointed out during the comment period. Discussion of this comment confirmed that the requirements should not depend on whether the SUPPLY MAINS is a.c. or d.c., but revealed a further anomaly. If ME EQUIPMENT is specified for connection to an extra-low voltage (ELV) SUPPLY MAINS (for example 12 V in an ambulance) but not to any higher voltage SUPPLY MAINS, the external voltage assumed for test purposes would be only the ELV. Such ME EQUIPMENT could however be used in locations where a higher voltage SUPPLY MAINS is also installed. The wording has therefore been revised to remove this anomaly.

If ME EQUIPMENT has a highest RATED supply voltage less than 100 V, it will necessarily be used in a special location where that supply is available, and we do not know what other supplies could also be present. Therefore the external voltage assumed for relevant tests is ~~250~~ 240 V, as for INTERNALLY POWERED ME EQUIPMENT.

~~However ME EQUIPMENT having a highest RATED MAINS VOLTAGE of around 115 V is unlikely to be used in locations having higher voltage SUPPLY MAINS, so the external voltage assumed for relevant tests is equal to the highest RATED MAINS VOLTAGE, as in the second edition of this standard.~~

Subclause 8.5.4 – WORKING VOLTAGE

The dielectric strength test voltages specified in Table 6 are appropriate for insulation that is normally subjected to a continuous WORKING VOLTAGE and to transient overvoltages.

The WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION is the voltage to which the DOUBLE INSULATION as a whole is subjected, because either MEANS OF PROTECTION can be subjected to this voltage if the other MEANS OF PROTECTION fails.

~~For insulation between two isolated parts or between an isolated part and an earthed part, the WORKING VOLTAGE could in some cases be equal to the arithmetic sum of the highest voltages between any two points within both parts.~~

For DEFIBRILLATION-PROOF APPLIED PARTS, a test voltage deduced on the basis of a WORKING VOLTAGE equal to the defibrillation peak voltage would be far too high for insulation that in NORMAL USE is exposed only occasionally to voltage impulses, normally shorter than ~~10~~ 1 s and without additional overvoltage.

Subclause 8.5.5 – DEFIBRILLATION-PROOF APPLIED PARTS

The special test described in 8.5.5 is considered to ensure sufficient protection against exposure to defibrillation pulses, no separate dielectric strength test being necessary.

Subclause 8.5.5.1 – Defibrillation protection

One or the other of the defibrillation paddles could, by virtue of its clinical application, be connected to earth or at least referenced to earth.

When a defibrillator is used on the PATIENT, a HIGH VOLTAGE can thus be impressed either between one part of the ME EQUIPMENT and another, or between such parts collectively and earth. ACCESSIBLE PARTS should be adequately isolated from PATIENT CONNECTIONS or protected in some other way. The insulation of the PATIENT CONNECTIONS cannot be protected by voltage limiting devices relying on earthed connections.

The DEFIBRILLATION-PROOF APPLIED PART marking indicates that an APPLIED PART can safely remain attached to a PATIENT who is being defibrillated without any adverse effect on subsequent use of the ME EQUIPMENT.

The tests ensure:

a) that any ACCESSIBLE PARTS of ME EQUIPMENT, PATIENT cables, cable connectors, etc. that are not PROTECTIVELY EARTHED will not deliver a hazardous level of charge or energy due to flashover of defibrillation voltage; and

b) that the ME EQUIPMENT will continue to function (at least with regard to BASIC SAFETY and ESSENTIAL PERFORMANCE) after exposure to defibrillation voltage.

The requirement and the test PROCEDURE refer to “any necessary time” stated in the ACCOMPANYING DOCUMENTS. There is no requirement for the ACCOMPANYING DOCUMENTS to include a statement of a recovery time, but if there is no statement the ME EQUIPMENT has to recover and deliver its BASIC SAFETY and ESSENTIAL PERFORMANCE immediately.

The tests are conducted with the ME EQUIPMENT connected to the SUPPLY MAINS and in operation according to the instructions for use because the tests deal not only with the effect of the defibrillation energy on BASIC SAFETY but also on the ability of the ME EQUIPMENT to deliver its ESSENTIAL PERFORMANCE after the stated recovery time.

NORMAL USE includes the situation that a PATIENT is defibrillated while connected to the ME EQUIPMENT and, at the same time, the OPERATOR or another person is in contact with the ENCLOSURE. The possibility of this occurring at the same time as the SINGLE FAULT CONDITION of a defective PROTECTIVE EARTH CONNECTION is very unlikely and is therefore disregarded. However, interruption of functional earth connections is more probable, and is therefore required for these tests.

The SEVERITY of electric shock that a person receives when touching ACCESSIBLE PARTS during the discharge of a defibrillator is limited to a value (corresponding to a charge of 100 μC) which can be felt and which could be unpleasant, but which is not dangerous.

SIGNAL INPUT/OUTPUT PARTS are included, as signal lines to remote ME EQUIPMENT could otherwise carry energies that might be hazardous.

The test circuits of Figure 9 and Figure 10 of this standard are designed to simplify the test by integrating the voltage appearing across the test resistance (R_1).

The value of the inductance L in the test circuits of Figure 9 and Figure 10 is chosen to provide a shorter than normal rise time in order to test adequately the incorporated protective means.

If ME EQUIPMENT would be designed according to 8.5.2.1 and 8.5.5.1, it might have two different functions on one common APPLIED PART circuit. Consider the example in Figure A.21. In this example, the ECG and an invasive blood pressure catheter (IBP) share one common APPLIED PART circuit. In real use in the hospital, sometimes only one function (ECG) is used while the other function (IBP) is not connected. If the PATIENT needs to be defibrillated, there is a potential that a second OPERATOR would get an electric shock at unused IBP outlets during selecting of proper adjustments at the ME EQUIPMENT (e.g. at a multi-parameter patient monitor). It should be pointed out that in principle, the 5 KV could occur at every disconnected connector, which does not have adequate recessed pins. However, in practice, the probability of occurrence of HARM is much higher at the unused APPLIED PART outlets on the ME EQUIPMENT compared to any connector of adapter cables. Adapter cables will normally not be touched by the OPERATOR during defibrillation, because before defibrillation the command “stand clear” will be given. Even in the case that a disconnected adapter cable would be touched by an OPERATOR during defibrillation, it will most probably be touched at the isolated plastic parts, but not at its internal pins.

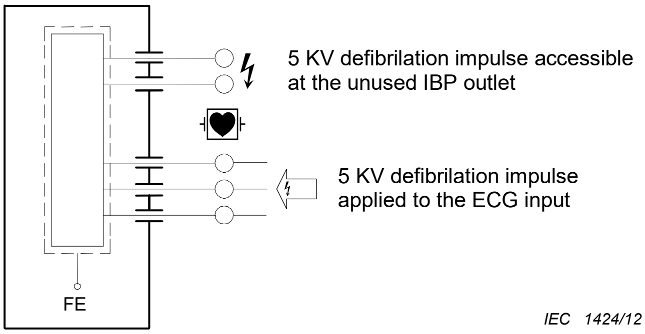


Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit

Rationale for impulse test voltage

When a defibrillation voltage is applied to the thorax of a PATIENT, via externally applied paddles (or defibrillation electrodes), the body tissue of the PATIENT in the vicinity of the paddles and between the paddles becomes a voltage dividing system.

The voltage distribution can be gauged roughly using three-dimensional field theory but is modified by local tissue conductivity that is far from uniform.

If the electrode of another item of ME EQUIPMENT is applied to the PATIENT, roughly within the compass of the defibrillator paddles, the voltage to which such an electrode is subjected depends on its position but will generally be less than the on-load defibrillation voltage.

Unfortunately it is not possible to say how much less as the electrode in question can be placed anywhere in this area, including immediately adjacent to one of the defibrillator paddles. In the absence of a relevant particular standard, it is required that such an electrode and the ME EQUIPMENT to which it is connected is able to withstand the full defibrillation voltage. This is the no-load voltage as one of the defibrillator paddles might not be making good contact with the PATIENT.

This standard therefore specifies 5 kV d.c. as the appropriate test voltage in the absence of a relevant particular standard.

Applying Subclause 4.5, a MANUFACTURER is allowed to use alternate means to address a RISK covered by this standard if the RESIDUAL RISK after applying the alternate means is equal or less than the RESIDUAL RISK after applying the requirements of this standard. It is possible for a MANUFACTURER to determine that a lower test voltage is appropriate depending on the INTENDED USE of the ME EQUIPMENT and the location of the APPLIED PARTS on the PAIENT if it can be demonstrated that the test voltage selected is the maximum voltage that can appear on the APPLIED PART with 5 kV applied to the chest. Such parts can be classified and marked as a DEFIBRILLATION-PROOF APPLIED PARTS.

Subclause 8.6 – Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

Typically, metal ACCESSIBLE PARTS of CLASS I ME EQUIPMENT are PROTECTIVELY EARTHED. However, they could be separated by other MEANS OF PROTECTION, in accordance with 8.5. Also some metal ACCESSIBLE PARTS could be earthed incidentally, neither by a PROTECTIVE EARTH CONNECTION nor for functional purposes. For example, such a part could be in contact with another part that is PROTECTIVELY EARTHED but does not itself need to be PROTECTIVELY EARTHED.

Subclause 8.6.1 – Applicability of requirements

PROTECTIVE EARTH CONNECTIONS that are only relevant to the safety of OPERATORS are allowed to comply either with the requirements of this standard or with those of IEC 60950-1:2005,