

Isolation Calculator 60601-1 Manual



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1 About the author

My name is Arno Morbach and I'm working as an electrical engineer. I'm in development of medical devices for more than 20 years now. With the development of every new device, the IEC 60601-1 is a major reason for discussion and attention. With the 3rd edition, I got the idea to simplify the task of determining the necessary air and creepage distances. It took some time but now the Android Isolation Calculator 60601-1 is ready for release.

This is my first Android program which means, that I had to learn a lot of new methods of programming. I'm experienced in Assembler or C programming but the object oriented approach was quite new to me. However, after some first obstacles were resolved, things got easier by the minute. The implementation of the calculation was the smallest problem. The interaction of the visible elements and file handling were the main tasks I had to solve.

You might have noticed that my native language is not English. I'm German, but since the IEC 60601-1 is an international standard I'm convinced that nearly every interested engineer is able to understand the english language. So this is the only language I'm documenting the app.

Comments, corrections or any other kind of feedback can be sent to
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Northern Germany, April 2014

2 Introduction

2.1 History of the IEC 60601-1

Medical devices which are driven by electrical power have to fulfill the international standard IEC 60601-1. The second edition of this standard has been established for quite a long time and the electrical engineers have been accustomed to it.

Things got complicated when the 3rd edition of the IEC 60601-1 was released in 2005. Suddenly parameters like operating altitude and isolation material characteristics were to be considered. The 3rd edition introduced a completely new approach for electrical safety in form of operator (MOOP) and patient (MOPP) protection.

In 2012 a new version of the IEC 60601-1 was released, edition 3.1. Regarding isolation, the only changes were the deletion of table 11 and an additional line for 25V in table 16.

Most engineers who have to design a medical device according to the IEC 60601-1 have to consider all three versions because not every country accepts the new versions of the standard. While some countries still use the 2nd edition, others require 3.0 or 3.1 to be fulfilled.

2.2 The Isolation Calculator 60601-1

The IEC 60601-1 (3.0 and 3.1) provides tables 11 to 16 to determine the necessary air and creepage distances for isolation barriers in a medical device. Test voltages can be read from table 6 and 7. To get the right values, many input parameters have to be considered. The Isolation Calculator helps to get the right values for air and creepage distance for all combinations of the three editions of the IEC 60601-1. It eases the calculation by asking for normal condition parameters as well as single fault parameters.

Proper documentation is an important task in the development of medical devices. The Isolation Calculator provides a text file export to include the calculation results in the isolation documentation.

3 Installation

The Isolation Calculator 60601-1 is tested for Android devices from version 2.1. to 4.4. The app is available at the Google Play Store and comes in two different versions.

The demo version is exactly like the standard version with one exception: On side 2 only voltage type primary can be selected, so that not all possible situations can be calculated. However the user can test and check all functions of the program before buying the standard version.

4 Overview

Figure 1 shows the screen of the Isolation Calculator after the start. The current screen is taken from the demo version. The icon in the upper left shows the word demo in red and the title is "Isolation Calculator DEMO!" instead of "Isolation Calculator 60601-1".

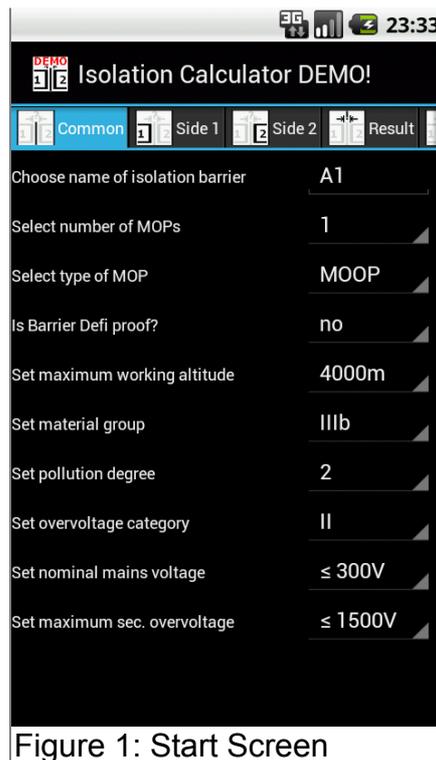


Figure 1: Start Screen

Under the title line, there are five tabs which select between the three input and the two output pages.

The tabs named "Common", "Side 1" and "Side 2" require input from the user. The Result of the calculation can be found on the "Result" tab. To get more information about intermediate calculation results, the tab "More" is provided. It is the rightmost tab in figure 1 and can be selected by shifting the tabs to the left.

The "Common" Tab collects all data which describe both sides of an isolation barrier in a medical device. The lower entry fields are likely to stay the same for all isolation barriers in a single device. For example the maximum operation altitude is the same for each electronics PCB in the device.

The tabs are explained in chapter 5.

5 Screen Layout

The screen is divided into five tabs which can be selected by pressing the tab titles. The active tab is marked by a blue color of the tab title.

The normal work flow to calculate isolation distances is left to right for the tabs and from top to bottom in each tab screen.

5.1 Common Tab

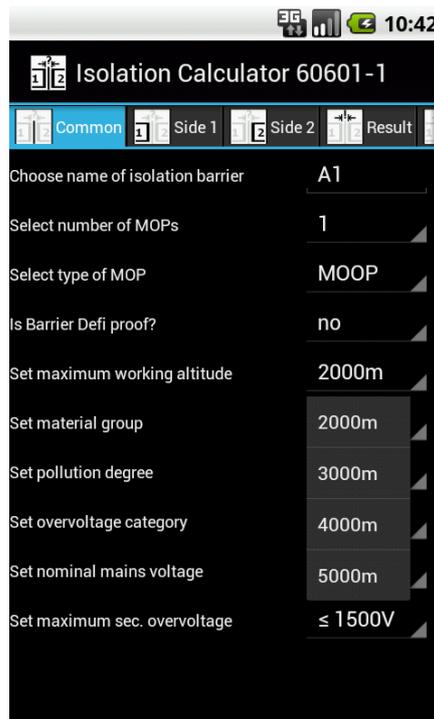


Figure 2: Common Tab

The first entry on the Common Tab is the name of the isolation barrier to be calculated. This is just for identification and the user can choose whatever he wants. The length is limited to 8 characters. Best practice would be to use the identification which is used in the isolation diagram of the device. See the example in Chapter 8.

All other entry fields offer certain choices which can be selected by the user. Figure 2 shows the Common Tab where the field for maximum working altitude has been pressed. A pop up selection allows choices of 2000m, 3000m, 4000m and 5000m. A long press on the text to the left produces a help screen which explains the entry field and points to the corresponding chapter in the IEC 60601-1.

5.1.1 Automatic default settings

There is a mechanism on some fields to prevent errors.

1. The fields *Select number of MOPs* and *Select type of MOP* are interconnected. If BOP is chosen, the number of MOPs will be automatically set to 1 because there is no rule for 2 BOP in the 60601-1.
If number of MOPs is set to 2, the type of MOP will automatically be set to MOOP out of the same reason as above.
2. Both fields *Set overvoltage category* and *Set nominal mains voltage* change the setting of *Set maximum sec. overvoltage*. According to chapter 8.9.1.12 of the IEC 60601-1 a secondary circuit will be one overvoltage category lower than the primary circuit. The user can still set another secondary overvoltage, but any change in *Set overvoltage category* and *Set nominal mains voltage* will recalculate this field again. If all settings are done from top to bottom, the user inputs will override this automatism.

5.2 Side 1 Tab, Side 2 Tab

For each side of an isolation barrier the expected voltages have to be given. This is done in the two tabs "Side 1" and "Side 2".

The top entry field requires the selection of a name. This name is not related to the calculation process but it documents which side of the isolation barrier is assigned to which part of the electrical circuit.

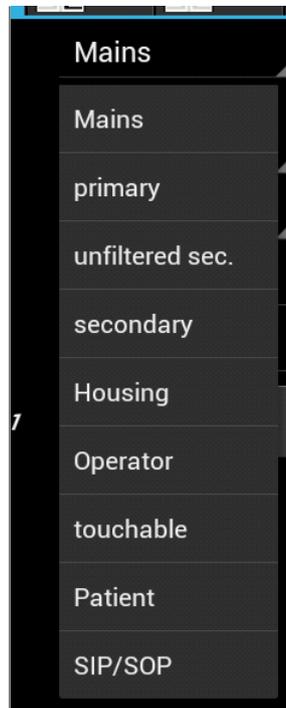


Figure 3: Choices for name of Side

Some of these choices are synonymous to each other but even if *Operator* and *Housing* might lead to the same setting, it can clarify the meaning of the given isolation.

The selection of *Select name of Side x* changes the default setting of the input fields of this screen. For example the setting *Patient* will lead to a normal condition of secondary voltage 10VAC and a single fault voltage of primary 240VAC. The user can change these default settings any time. They will only be overwritten if *Select name of Side x* is changed.

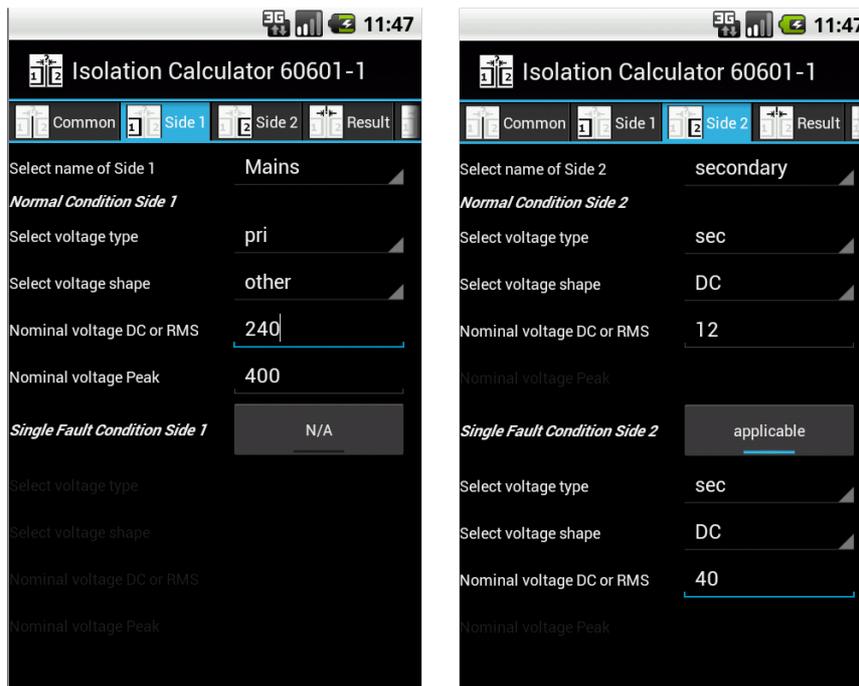


Figure 4: Side 1 and Side 2 Tab

For each side of the isolation barrier a voltage for normal condition has to be given. It is also possible to set values for the single fault condition if it exists. The button *Single Fault Condition Side x* toggles between *applicable* and *N/A*. The input fields are greyed out if no input is needed.

The same is true for the *Nominal voltage Peak* field. It is only visible if the voltage shape is set to *other*. Peak voltage of DC is the same as the DC voltage and peak voltage of AC is $\sqrt{2} * \text{AC RMS voltage}$. The IEC 60601-1 requires DC or RMS values for some tables, but it also requires peak voltages. If the voltage is not sinusoidal or DC, *other* has to be chosen and the values for RMS and peak voltage must be set.

5.3 Result Tab

When all settings for the isolation barrier are done, the user can switch to the Result Tab to see which air and creepage distances are needed. Also the necessary test voltage is shown.

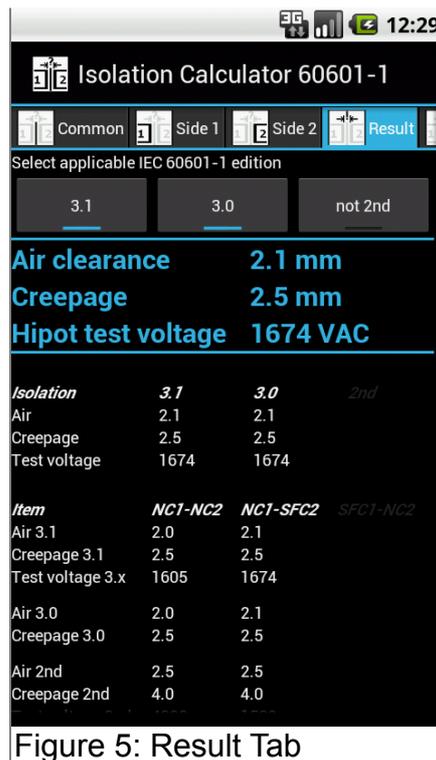


Figure 5: Result Tab

The user can select for which version of the IEC 60601-1 the calculation shall be done. The three toggle buttons on the top select the appropriate editions of the standard. The blue results are always the maximum values of the different calculations for the selected standards and the different working conditions.

Figure 5 shows a result page for the editions 3.0 and 3.1 of the IEC. The table in the middle shows the individual results of the calculations for the different IEC editions. Because of the setting of the toggle button on top, only results for 3.0 and 3.1 are shown (and calculated).

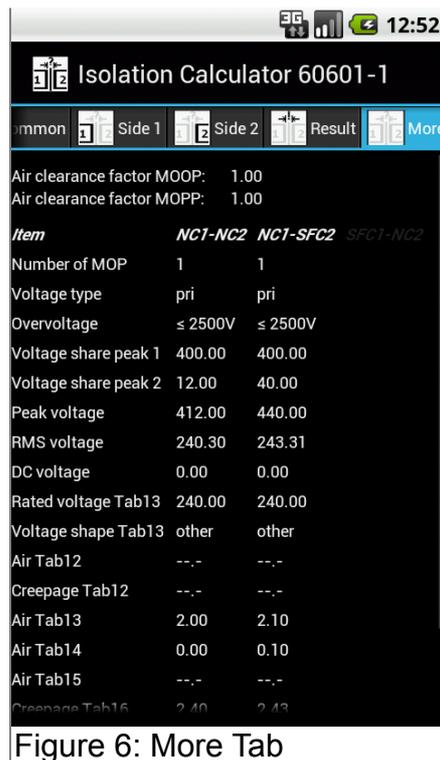
The table in the lower part of the screen shows the individual results for each IEC edition and the different working conditions. The column NC1-NC2 shows the results for the normal condition. Column NC1-SFC2 shows the result for normal condition on side 1 and single fault condition on side 2. Since no single fault was given for side 1, the last column which would provide these values is greyed out.

Figure 5 shows that the result values are the same for edition 3.0 and 3.1. But it also shows, that the test voltage of 1674VAC is caused by the single fault condition on side 2. Otherwise only 1605VAC would be needed. This is similar to the air distance. 2.0mm air distance would be enough if no single fault condition would exist.

The result is updated any time one of the three toggle buttons is changed. The user can also switch to one of the input tabs to change settings. The Result Tab will always provide the result of the current calculation.

5.4 More Tab

Sometime it is useful to know how a certain result was calculated. The More Tab provides some internal results to show intermediate results of the calculation.



Like in the other screens a long press on the text to the left produces a help screen which explains the field and the calculation behind it. This screen is an output only, there are no entries to be done here.

6 Help

Nearly every text in the left column of each tab screen contains some help function. A long press on the text pops up a help screen which explains the purpose of the line. The back button, available on all Android devices, closes the help screen and comes back to the tab screen.

7 Menu

On any screen a press of the menu button (on older Android devices is it a hardkey, on newer devices the menu button is on the upper right corner of the display) brings up a menu to manage the current calculation. Most menu commands are used to save or reload information. Chapter 7.1 gives a short overview about the different levels of data storage.

7.1 Data handling

Data are managed in three levels:

1. The user changes or enters data on any of the three input tabs. These data are automatically saved when the program is closed. They are reloaded when the Isolation Calculator is started again.
2. To save the data set of a certain isolation barrier, the menu *Save isolation 'x'* is used. This adds an entry in the current database. This database is also automatically

saved when the program is closed. The database will contain several sets of isolation barrier data which can be handled by the menu commands *Load isolation barrier* and *Delete isolation barrier*.

3. Usually, the current database should only consist of entries for a single medical device. To be able to handle data from several medical devices, back ups can be made from the current database. The menu commands *Backup database* and *Restore database* allow to manage database files from multiple devices. The current database can also be exported as a CSV-file for documentation purposes.

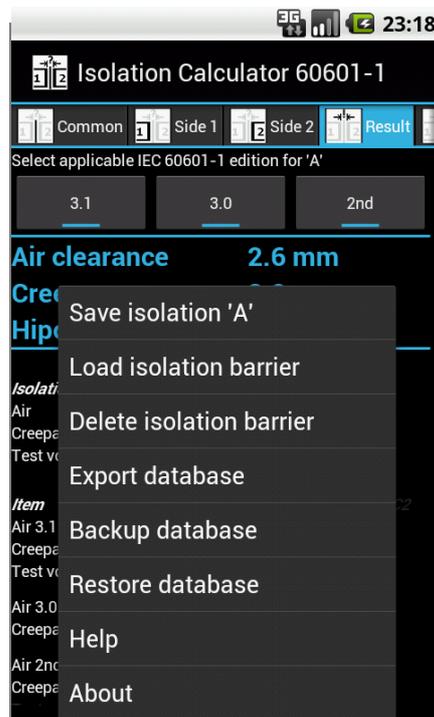


Figure 7: Menu

7.2 Save isolation 'x'

The current calculation of an isolation barrier can be saved for later use. The menu button shows the name which will be used for storage. This is the entry from the first line of the Common Tab.

Storage is done in an internal database which collects all subsequent save actions. If an isolation barrier with the current name already exists, the user is prompted if he wants to overwrite it.

7.3 Load isolation barrier

If a certain saved isolation barrier calculation shall be edited or viewed again, it can be loaded by the *Load isolation barrier* command of the menu. A selection of all saved data sets is presented to the user and he can choose the right one. The current settings will be overwritten by the loaded values.

7.4 Delete isolation barrier

If a saved entry of an isolation barrier is no longer needed, it can be deleted with the *Delete isolation barrier* command of the menu. In addition to all saved data sets, a selection with *--delete all--* is selectable. This will delete all entries and produce an empty database.

7.5 Export database

Very important for documentation purposes is the *Export database* command of the menu. All saved isolation barrier calculations can be exported into a CSV-file on the memory of the Android device. This file can then be copied onto any other computer system. The file uses Unicode fonts to be able to use the "≤" symbol.

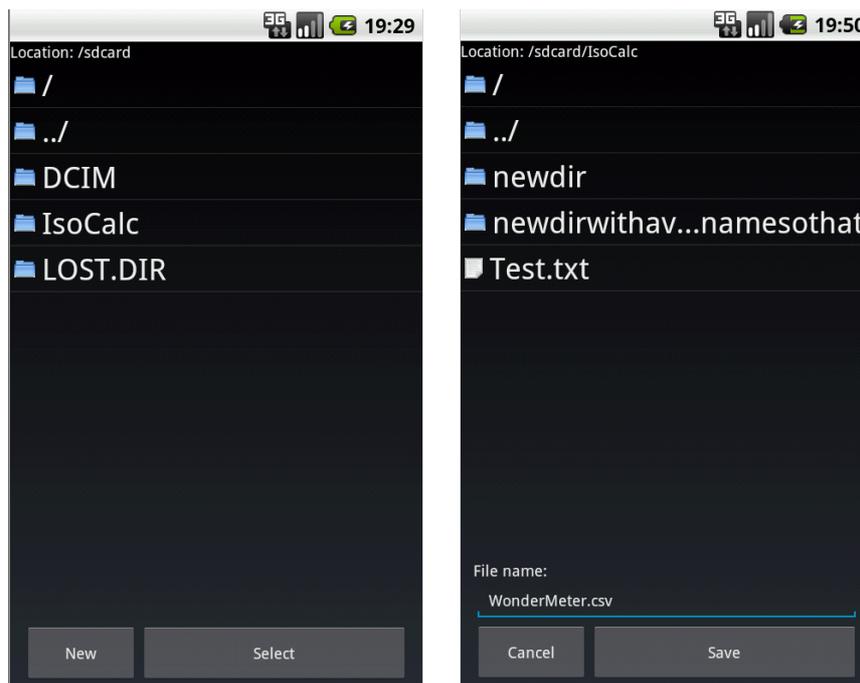


Figure 8: Export dialog

The user can click on the directories to navigate through the memory. In the left screen in figure 8 the user pressed the *IsoCalc* directory and then the *New* button on the bottom. This lead to the screen on the right. Now the name of the medical device is entered and with a press on *Save* the file is written to */sdcard/IsoCalc/WonderMeter.csv*.

If a new directory should be created just write the new name in front of the filename. Figure 9 shows an example where a file *Device1.csv* is created in the directory */sdcard/Isocalcnew*.

The names of the external memory in an Android device are not very well defined. They differ from device to device. Some kind of file manager app can be used to browse the memory of the device to find a suitable storage location.



Figure 9: Creating a new directory

Note: Only saved data sets are exported. If an isolation barrier with the name **A** has been saved and then changed again, the export function will export the saved data. The current data set is not used for export, it is a temporary collection of data until it gets saved.

7.6 Backup database

If calculations for several devices shall be done with the Isolation Calculator it is convenient to separate the data sets into different files. The *Backup database* command enables the user to store the current set of calculations into a file. The command works similar to the *Export database* command with the exception that the result is a SQLite database and that the ending *.isocalc* is automatically added to the given filename. This file should not be altered and only be used for backup usage. It can later be read back by the *Restore database* command.

7.7 Restore database

A previously stored database can be restored. A file selection dialog appears and all *.isocalc* files are listed in the selected directory. After navigating to the desired directory, the file name is clicked and then the *Select* button is pressed. The database will then be loaded. Now new isolation barriers can be entered or already existing ones can be changed.

Warning: Restoring of databases is a simple copy function. The program does not check if the data are correct. The program may crash if the files have been changed in any way. Maybe this will be improved in later releases.

7.8 Help

Some simplified help can be found here. The main issues of the Isolation Calculator are explained in a condensed description.

7.9 About

Here you can find some version and contact information.

8 Examples

With an imaginary device the use of the Isolation Calculator 60601-1 is explained. Figure 10 serves as the source for the calculation.

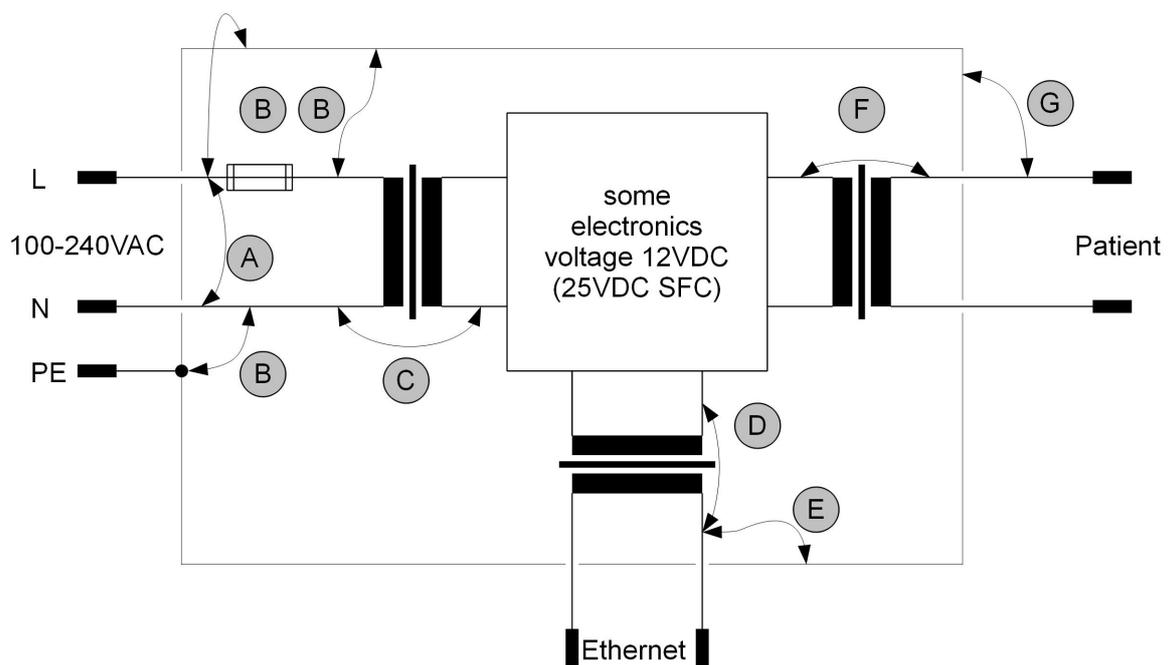


Figure 10: Isolation diagram of an imaginary device

The device is a class I device with protective earth connection. The internals are simplified to only show the isolation barriers. The transformer symbols are used to represent any kind of isolation for the signals. In reality this can also be an optocoupler, a transformer or a Y-capacitor or any combination of these.

It is assumed that the device has to be able to be used up to an altitude of 4000m. It is used in a hospital (pollution degree 2, overvoltage category II). The applied part is not defi proof and the PCB material is standard FR4.

8.1 Isolation barrier A

First, any old calculation results are erased. To do this, use the *Menu* button and the command *Delete*. In the Delete dialog choose *--delete all--* to erase all existing data in the database.

To enter the data of the first isolation barrier **A** the following values are used in the Common tab (figure 11).

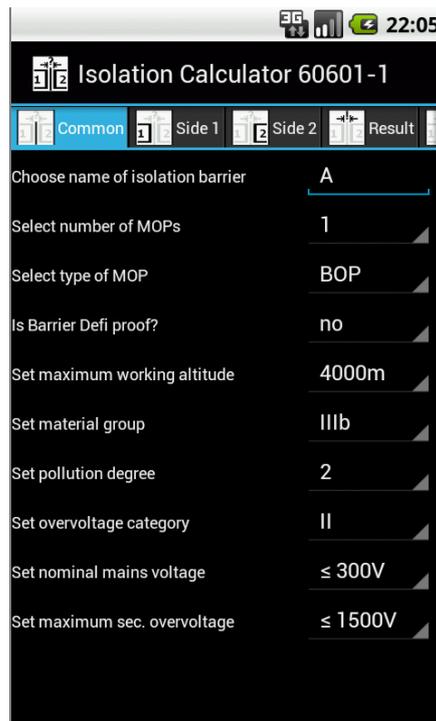


Figure 11: Common settings for A

Figure 12 shows the settings for side 1 and side 2. In this case, these are the values for L and N of the mains voltage. This is the only unusual case where the voltages between the two sides come from single lines. All other isolation barriers in the isolation diagram will be handled in another way, but this can be seen later in the other examples.

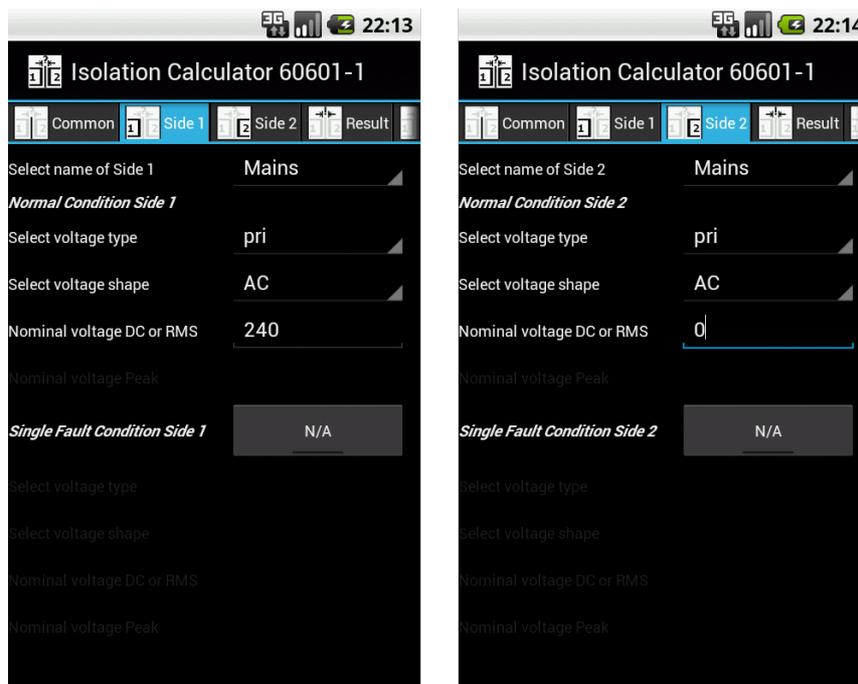


Figure 12: Settings for A, side 1 and 2

For BOP, there is no single fault condition to be regarded, so both toggle buttons are set to N/A.

After the three input tabs have been filled with the correct data, a click on the Result tab will show the necessary air and creepage distances for the **A** barrier (figure 13).

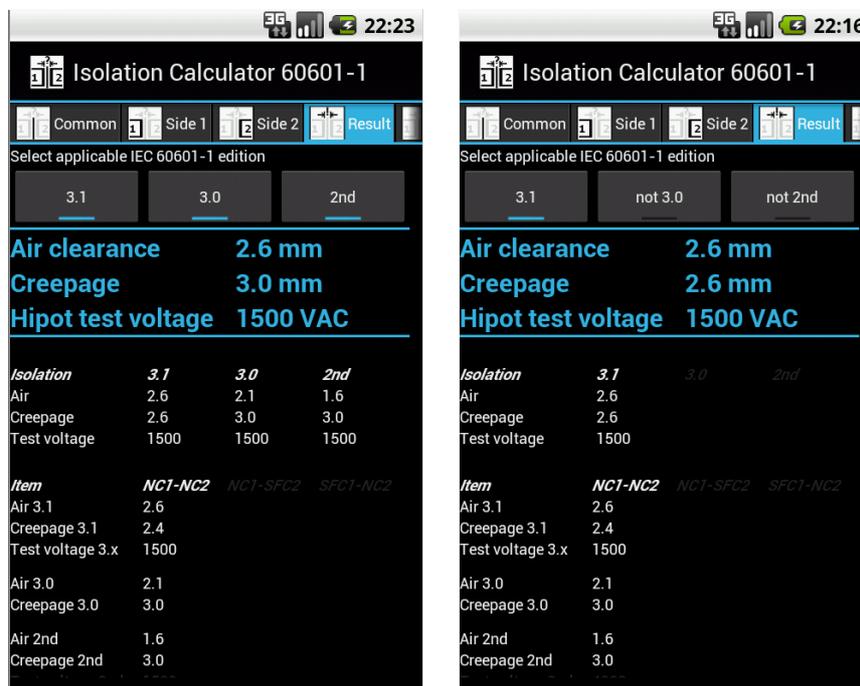


Figure 13: Results for A (left all editions, right only 3.1)

Figure 13 shows two different result pages. They differ in the setting of the three toggle switches on the top. The left screen shows the result for **A** for all three editions of the IEC 60601-1. The table in the middle shows that the air clearance of 2.6mm is governed by the 3.1 edition. The 3.0 requires only 2.1mm and the 2nd edition only 1.6mm.

However, the creepage distance is ruled by the 3.0 or the 2nd edition with 3.0mm. The 3.1 only requires 2.6mm.

This example demonstrates that it is not the safe way to use the 3.1 edition for all applications. If a certain country does not accept the 3.1 it may still demand a creepage distance of 3.0mm. And even that the 3.1 uses MOOP instead of BOP (this is automatically considered by the Isolation Calculator) means that the 3.0 edition requires more creepage than the 3.1.

It's up to the user which standard has to be fulfilled. The right screen shows a result for the 3.1 edition only. Note the two right toggle buttons. They are set to *not 3.0* and *not 2nd* to disable the calculation of these results.

The 3.0 and 3.1 contain no differences in regard to the test voltage. So these two will always be the same. But of course the 2nd edition result could be different. In the **A** case, all editions of the IEC 60601-1 come to the same value of 1500VAC.

This example shows a limitation of the Isolation Calculator: It can help to get the correct values from the different look up tables, but it can not know if a certain test voltage is really feasible in the medical device. In this case a test voltage makes no sense. It could harm

the electronics or the test would fail because of high current. The user still has to assess if a calculated test voltage really can be applied to an isolation barrier.

The table in the lower third of the screen provides only one column with intermediate results because there are no settings for any single fault conditions.

To keep this result for later use, it should be saved. A click on the *Menu* button of the Android device shows the following screen.

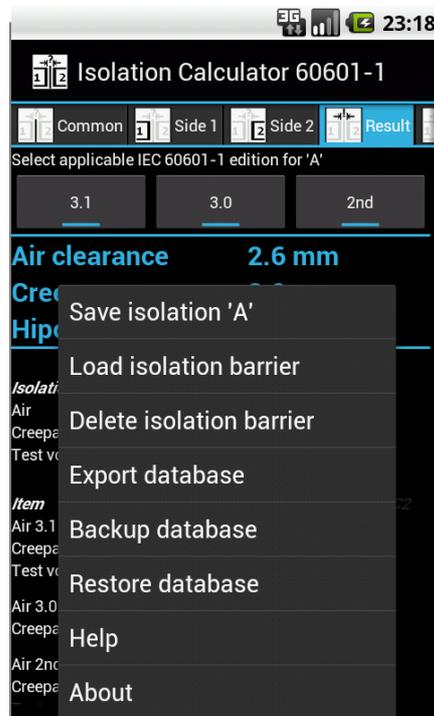


Figure 14: Menu to save data

The top menu item can be used to save the current data set in an internal data base. If the name is not already used, the data are stored. Otherwise a dialog appears to ask if the existing entry in the database shall be overwritten.

Now, all necessary steps to calculate the data for barrier **A** have been done.

8.2 Isolation barrier B

To enter the data for **B** the user clicks on the Common tab to change the appropriate entry fields. The only changes are the name and the type of the isolation barrier. Now it is MOOP because it is assumed, that the housing of the medical device is only accessible by an operator and not by a patient.

As in most cases, the lower entry fields of the Common tab stay the same because they are related to the whole device and not to a specific isolation barrier.

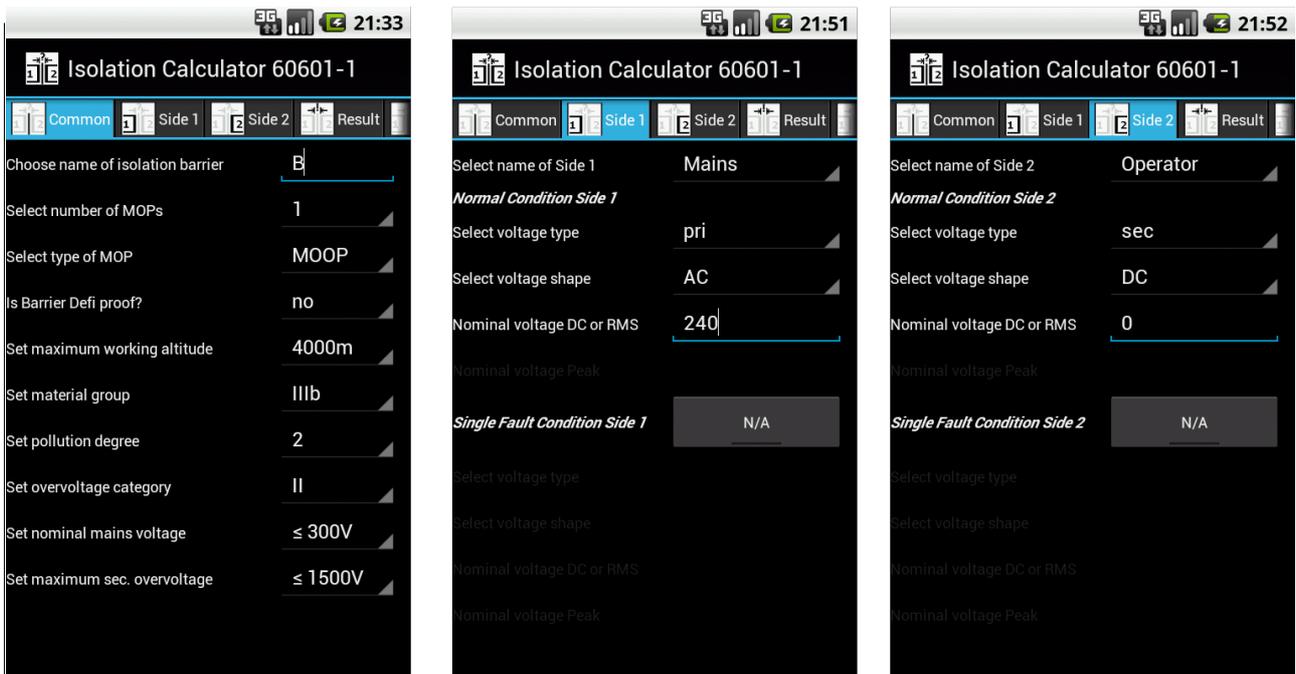


Figure 15: Input values for B

Like for **A**, there are no single fault conditions for barrier **B**.

This time, the results for the edition 3.0 and 3.1 are the same. But again, the values for the 2nd edition are different. The 2nd edition requires a higher creepage distance.

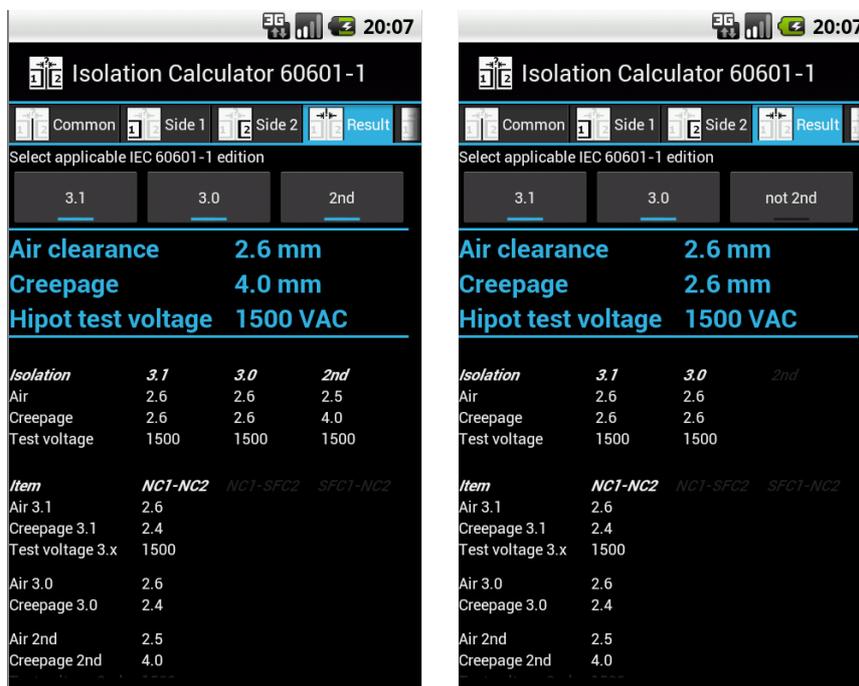


Figure 16: Results for B (left all editions, right 3.0 and 3.1)

8.3 Isolation Barrier F

The last example shows the calculation for isolation barrier **F**. This assumes that the mains transformer with barrier **C** already provides adequate isolation from mains. The settings of all other isolation barriers in figure 11 are listed in chapter 8.4.

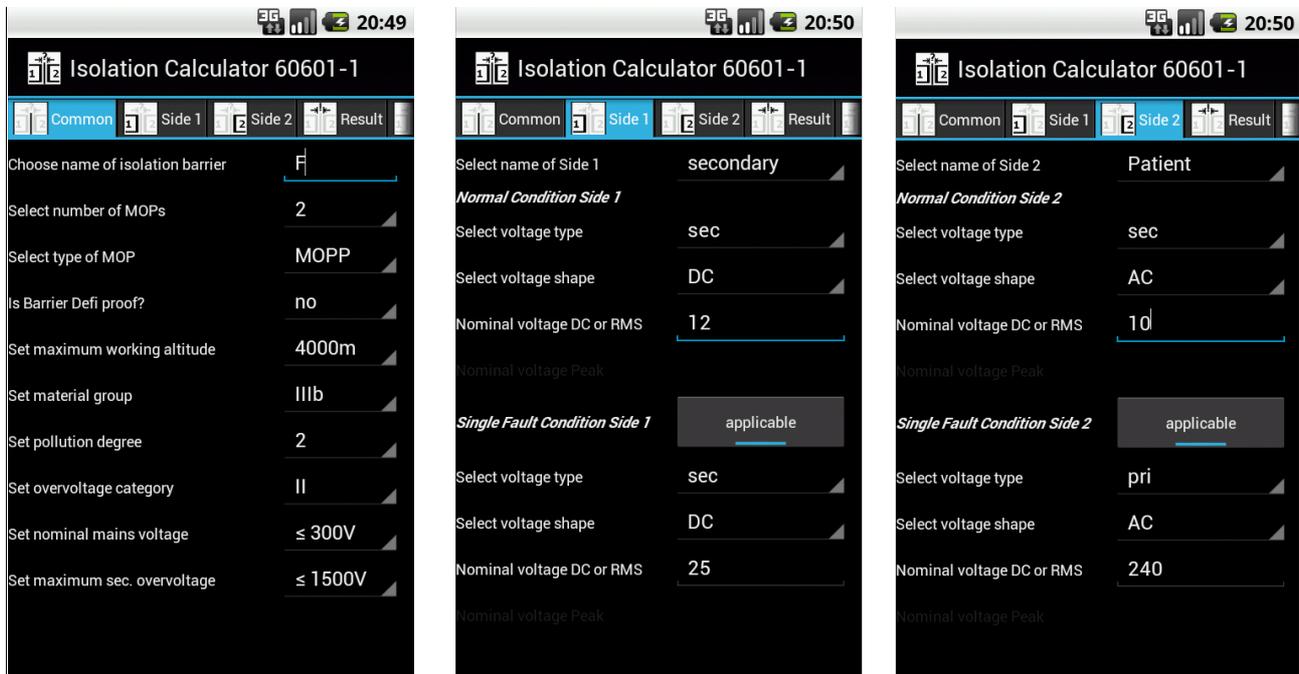
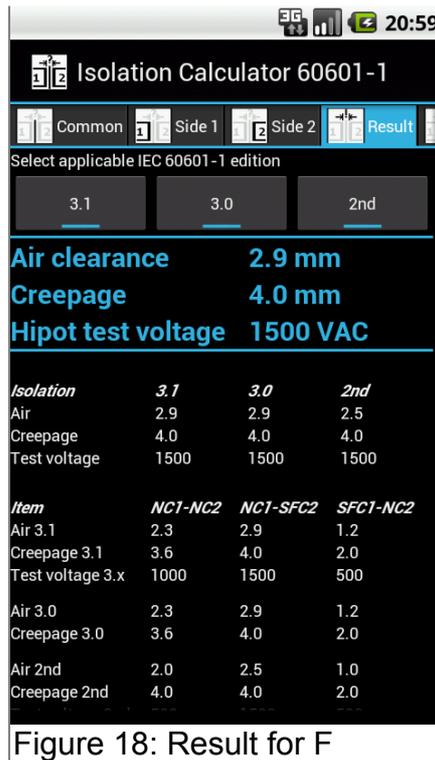


Figure 17: Input values for F

Here two single fault conditions are to be considered. The calculator includes all three possible situations to get the maximum values for the isolation distances. Figure 17 shows the input settings for **F**.

The lower part of the Result tab (figure 18) shows the three intermediate results. NC1-NC2 is calculated using 2 MOPP because this was set in the Common Tab. But the values for NC1-SFC2 are higher although the calculation for a single fault is only done with 1 MOPP. This is because of the high single fault voltage of 240VAC.

Single fault calculations are always done for 1 MOP regardless of the setting of the *Select number of MOPs* field because it is assumed that one MOP has already been broken but this will be noticed in short time, so that this hazardous situation will be corrected.



8.4 Listing of all settings

The next two tables list all settings of the example. The values have been input into a spread sheet and formatted for better reading. The exported file consists of 45 columns. It is split into two halves which are shown in the next two tables.

Name	3.1	3.0	2nd	Number of MOPs	Type of MOP	Defi proof	Altitude	Material	Pollution	OV Category	Nominal mains	Sec. OV	Name Side 1	voltage type NC1	voltage shape NC1	RMS voltage NC1	Peak voltage NC1	SFC1	voltage type SFC1	voltage shape SFC1	RMS voltage SFC1	Peak voltage SFC1
A	3.1	3.0	not 2nd	1	BOP	no	4000m	IIIb	2	II	≤ 300V	≤ 1500V	Mains	pri	AC	240	N/A	N/A	N/A	N/A	N/A	N/A
B	3.1	3.0	not 2nd	1	MOOP	no	4000m	IIIb	2	II	≤ 300V	≤ 1500V	Mains	pri	AC	240	N/A	N/A	N/A	N/A	N/A	N/A
C	3.1	3.0	not 2nd	2	MOPP	no	4000m	IIIb	2	II	≤ 300V	≤ 1500V	Mains	pri	AC	240	N/A	N/A	N/A	N/A	N/A	N/A
D	3.1	3.0	not 2nd	2	MOOP	no	4000m	IIIb	2	II	≤ 300V	≤ 1500V	SIP/SOP	sec	DC	5	N/A	applicable	pri	AC	240	N/A
E	3.1	3.0	not 2nd	1	MOOP	no	4000m	IIIb	2	II	≤ 300V	≤ 1500V	SIP/SOP	sec	DC	5	N/A	applicable	pri	AC	240	N/A
F	3.1	3.0	not 2nd	2	MOPP	no	4000m	IIIb	2	II	≤ 300V	≤ 1500V	secondary	sec	DC	12	N/A	applicable	sec	DC	25	N/A
G	3.1	3.0	not 2nd	2	MOPP	no	4000m	IIIb	2	II	≤ 300V	≤ 1500V	Patient	sec	AC	10	N/A	applicable	pri	AC	240	N/A

Table 1: Exported values (left)

Name Side 2	voltage type NC2	voltage shape NC2	RMS voltage NC2	Peak voltage NC2	SFC2	voltage type SFC2	voltage shape SFC2	RMS voltage SFC2	Peak voltage SFC2	Result air clearance	Result creepage	Result test voltage	air clearance 3.1	creepage 3.1	test voltage 3.1	air clearance 3.0	creepage 3.0	test voltage 3.0	air clearance 2nd	creepage 2nd	test voltage 2nd
Mains	pri	AC	0	N/A	N/A	N/A	N/A	N/A	N/A	2.6 mm	3.0 mm	1500 VAC	2.6	2.6	1500	2.1	3.0	1500	N/A	N/A	N/A
Operator	sec	DC	0	N/A	N/A	N/A	N/A	N/A	N/A	2.6 mm	2.6 mm	1500 VAC	2.6	2.6	1500	2.6	2.6	1500	N/A	N/A	N/A
secondary	sec	DC	12	N/A	applicable	sec	DC	25	N/A	5.7 mm	7.9 mm	4000 VAC	5.7	7.9	4000	5.7	7.9	4000	N/A	N/A	N/A
secondary	sec	DC	12	N/A	applicable	sec	DC	25	N/A	2.6 mm	2.6 mm	1500 VAC	2.6	2.6	1500	2.6	2.6	1500	N/A	N/A	N/A
Housing	sec	DC	0	N/A	N/A	N/A	N/A	N/A	N/A	2.6 mm	2.6 mm	1500 VAC	2.6	2.6	1500	2.6	2.6	1500	N/A	N/A	N/A
Patient	sec	AC	10	N/A	applicable	pri	AC	240	N/A	2.9 mm	4.0 mm	1500 VAC	2.9	4.0	1500	2.9	4.0	1500	N/A	N/A	N/A
Housing	sec	DC	0	N/A	N/A	N/A	N/A	N/A	N/A	2.9 mm	4.0 mm	1500 VAC	2.9	4.0	1500	2.9	4.0	1500	N/A	N/A	N/A

Table 2: Exported values (right)

9 Theory of operation

9.1 Sequence of calculation

Figure 19 tries to show the dependencies of the calculated results from the input values. The calculation is done in four steps.

1. For each condition (NC1-NC2, NC1-SFC2 and NC1-SFC2) the working voltages are calculated. This includes the voltage type (primary, secondary or unfiltered secondary). Primary dominates over unfiltered secondary which dominates over secondary. If both sides have different voltage types, the dominating type is used for calculation.
Peak working voltage is the sum of the peak voltages. DC working voltage is the sum of the DC voltage or 0 if not purely DC. RMS is the square root of the sum of the squares of the RMS values. This is in accordance with the IEC 60950 (chapter 2.10.2.2) which is not explicitly mentioned in the IEC 60601-1.
2. The working voltages in combination with other input values are used to get the appropriate results of the tables of the IEC 60601-1. Figure 19 shows only the dependencies for the NC1-NC2 condition. MOPP dominates over MOOP, so table 12 is used whenever MOPP is set in the Common Tab.
3. The table readouts are then again combined with input values (altitude and Defi Proof) to provide the final results.
4. As a very last step, the creepage distance is compared to the air distance. If it is lower, then the air clearance is taken, because the creepage distance can not be less than the air clearance.

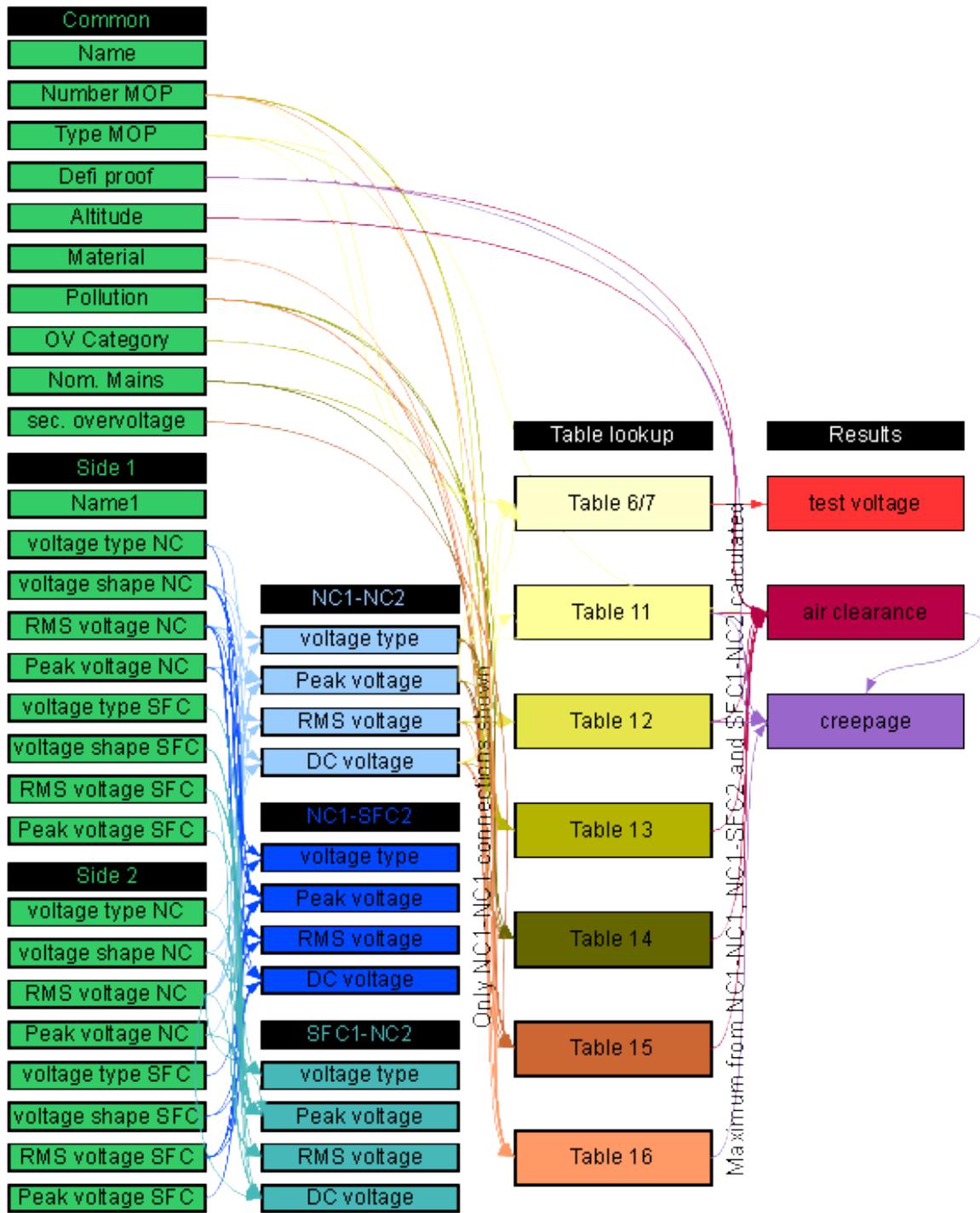


Figure 19: Dependencies for the 3rd edition of the IEC 60601-1

9.2 Voltage type: primary / unfiltered secondary / secondary

The IEC standard distinguishes between primary and secondary voltages. However, sometimes a voltage on the secondary side of a transformer still has to be considered like a primary voltage because of transients. On the other hand, test voltages do not depend on possible overvoltages. To help finding the correct values, the term "unfiltered secondary" is introduced in this calculator: This is a secondary voltage which still can be subject of primary side overvoltage transients. For examples please see figure 20.

The secondary side of a normal transformer without any additional means to attenuate primary transient voltages shall be given as unfiltered secondary in the entry fields.

If there is an effective filter on the secondary side, this voltage shall be given in the Input sheet as secondary.

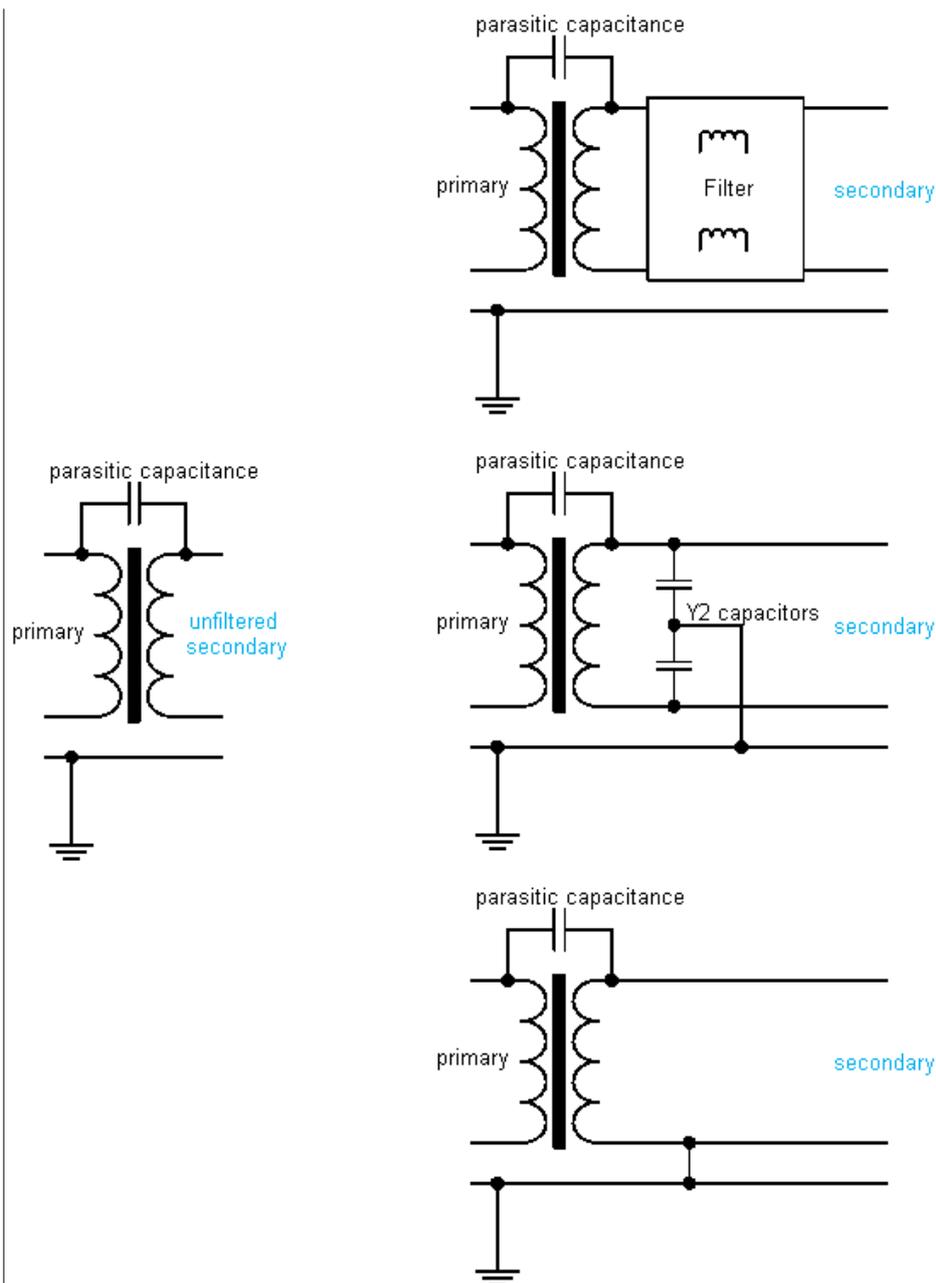


Figure 20: Difference between unfiltered secondary and secondary

A filter is effective when it leads to transient overvoltages one class lower than the class of the primary circuit. The calculator determines this value automatically in the entry field *set maximum sec. overvoltage* of the Common tab, but it can be changed to other values manually, for example to "none" or " $\leq 800V$ ". Generally, such a lower value must be justified by tests.

For MOOP, both voltage types primary and unfiltered secondary are treated the same and the air distances are calculated using table 13 and 14. Air distance for voltage type secondary is calculated using table 15.

For MOPP, there is no differentiation of voltage type. Table 12 is used for air clearance and creepage distance.

9.3 Table 6 and Table 7

There is a discrepancy in table 6. The first row is for peak voltages up to 42.4V and DC voltages up to 60V. The second row provides test voltages for up to 71V regardless of Peak or DC voltage. For a secondary circuit providing two MOPP this leads to the following situation: A working voltage of 50VDC would use the first row and require 1000V test voltage. But a sinusoidal voltage of 35,3V has a peak voltage of 50V and this would use the second row requiring 1500V test voltage.

Another issue is table 7 which begins at voltages of 34 V although table 6 refers to it only for voltages above $42,4V_{\text{peak}}$ or 60VDC respectively. The example above (now for MOOP) would lead to no test for the 50VDC but 957V test voltage for the 35,3VAC ($50V_{\text{Peak}}$).

The Isolation Calculator works like follows: If the working voltage is DC, the DC look up values are used. And even though no test voltage is required by table 6 a minimum of 500V (1 MOOP) or 800V (2 MOOP) is given. According to table 7, the test voltage rises up to 42,4VDC. Then it stays until 60VDC is reached. Then it follows table 7 again.

If the working voltage type is AC or other, the peak voltage is used for look up. It follows table 7 to calculate the test voltage beginning at 34V.

This approach may lead to slightly higher test voltages than necessary, but it also avoids any discussion with external authorities. It is up to the user to decide if a certain test voltage should be applied.

9.4 Table 13 and Table 14

Table 13 and 14 of the third edition IEC 60601-1 are quite complicated to understand. It took some time and a lot of discussions to come up with an interpretation of these new tables. The origin of these two tables is the IEC 60950-1 with tables 2K and 2L. Both tables require input values as peak voltages. But if both tables would require the same input they could be combined into one single table. The web page <https://www.mail-archive.com/emc-pstc@listserv.ieee.org/msg42710.html> describes the situation quite good. The peak voltage used in table 13 is the mains peak voltage and the value used for table 14 is used if a higher peak voltage is present across the isolation barrier.

The Isolation Calculator solves this in the following manner:

Any isolation barrier consists of two sides which are characterized as primary, unfiltered secondary or secondary. The table below shows how the input values are used in table 13 and 14.

Side 1	Side 2	Used in table 13	Used in table 14
U1 primary	U2 primary	$\max(U1_{\text{peak}}, U2_{\text{peak}})$	$U1_{\text{peak}} + U2_{\text{peak}}$
U1 primary	U2 unf. secondary	$U1_{\text{peak}}$	$U1_{\text{peak}} + U2_{\text{peak}}$
U1 primary	U2 secondary	$U1_{\text{peak}}$	$U1_{\text{peak}} + U2_{\text{peak}}$
U1 unf. secondary	U2 primary	$U2_{\text{peak}}$	$U1_{\text{peak}} + U2_{\text{peak}}$
U1 unf. secondary	U2 unf. secondary	$\max(U1_{\text{peak}}, U2_{\text{peak}})$	$U1_{\text{peak}} + U2_{\text{peak}}$
U1 unf. secondary	U2 secondary	$U1_{\text{peak}}$	$U1_{\text{peak}} + U2_{\text{peak}}$
U1 secondary	U2 primary	$U2_{\text{peak}}$	$U1_{\text{peak}} + U2_{\text{peak}}$
U1 secondary	U2 unf. secondary	$U2_{\text{peak}}$	$U1_{\text{peak}} + U2_{\text{peak}}$
U1 secondary	U2 secondary	<i>not applicable</i>	<i>not applicable</i>

Table 3: Values for table 13 and 14

So, the more harmful voltage type (primary → unf. secondary → secondary) specifies the value for table 13. If the types are the same on both sides, the higher value is chosen. This situation should be very unusual but the Calculator will chose the worst case values. With the knowing of the table above, the user can force the Isolation Calculator to provide correct results by adjusting the voltage types correspondingly.

9.4.1 Special example: switched mode power supply

A switched mode power supply (SMPS) like in figure 21 can be a challenge for getting the right data. With the knowledge of table 3 it is possible to calculate the air clearance and creepage distance by inserting precalculated values into the entry fields. The goal is to get the 240VAC as look-up for table 13 and the correct peak (table 14) and RMS (table 16) values.

With side 1 as 240VAC and primary, this results in $240V_{\text{RMS}}$ and $339,4V_{\text{peak}}$. Side 2 is set as unfiltered secondary, so the Calculator uses the side 1 peak value for look-up. To get the $480V_{\text{peak}} + 48V_{\text{peak}} = 528V_{\text{peak}}$ for table 14, side 2 must be set to voltage type *other* with a peak value of $528V - 339,4V = 189V_{\text{peak}}$. To get correct values for the creepage distance, the RMS value for side 2 must be set to $\sqrt{(350+35)^2 - 240^2} = 301V$. The Isolation Calculator will do a backwards calculation and the result will be the $385V_{\text{RMS}}$ across **J**.

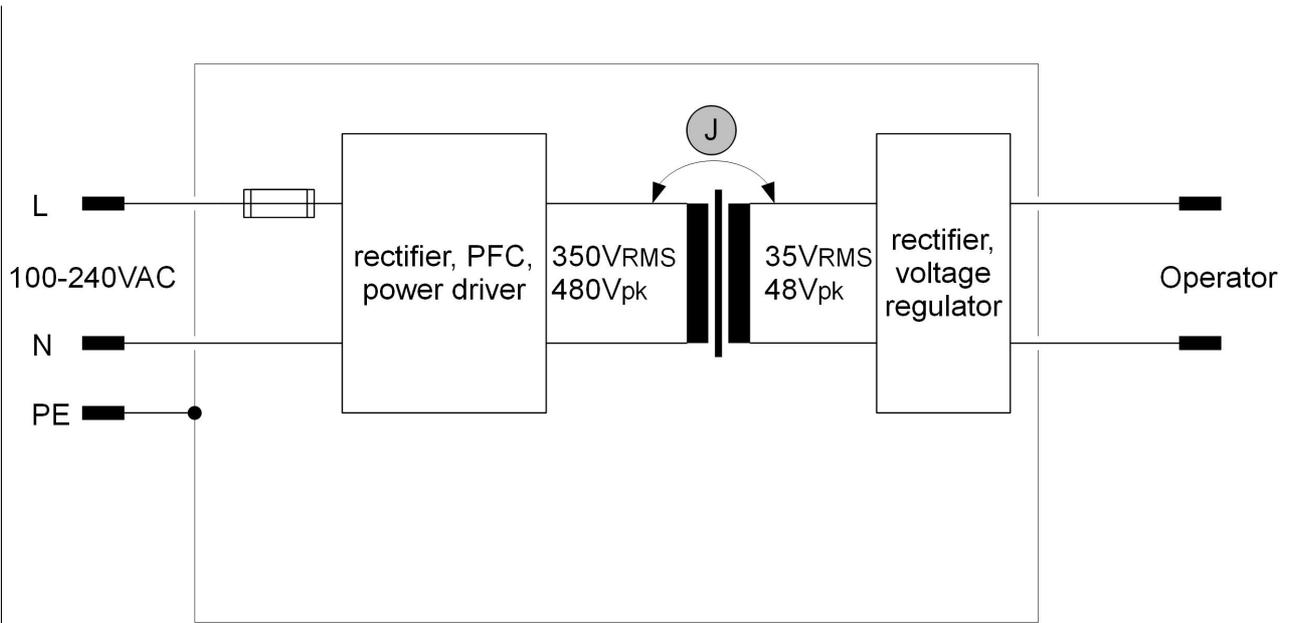


Figure 21: Internals of a SMPS

Such a situation is rare and it would be confusing if the Isolation Calculator would offer the possibility to enter this kind of data directly.

9.5 Error handling

It is possible to enter exorbitant data into the voltage entry fields. The different tables of the IEC end at different voltage levels. This tool was written for people who do real work for real medical devices. So, until now I didn't insert any function for checking of meaningful input settings. However if a voltage value exceeds the range of a look up table, it produces a value above 900mm air or creepage distance. This will be the sign that something is wrong with the input data.

9.6 Table look up and interpolation

9.6.1 Air clearance

For air clearances no interpolation of table look up values is allowed (chapter 8.9.1.6, 3rd edition). After multiplication with the necessary factors of table 8 (chapter 8.9.1.5, 3rd edition) the result is rounded to the next higher 0,1mm increment.

9.6.2 Creepage distance

The IEC 60601-1 3rd allows interpolation for creepage distances (chapter 8.9.1.6). The calculator uses this possibility to provide results which are not unnecessary high.

For the 2nd edition, no interpolation of creepage distances is done.

9.6.3 Test voltages

The tables 6 and 7 (3rd edition) and table 5 (2nd edition) for test voltages are a mixture of dedicated values and formulas to get the test voltages. In the Isolation Calculator precalculated tables are used which can lead to slightly different results. The values for MOPP and peak voltages above 354V are taken from an extended table where the formulas are inserted.

To be on the save side, the given results are always higher or equal to the formula calculated values. The difference is in the range of less than 2%. For example, a working voltage of $360V_{peak}$ for MOPP needs a test voltage of 4019VAC. Any voltage between $360V_{peak}$ and $370V_{peak}$ results in 4047V test voltage. The deviation of 28V is insignificant, it is less than 0,7%.

10 Revision History

Version	Date	Remarks
1.0	2014-04-04	First official version
1.1	2014-05-02	Chapter 9.3 added

11 Disclaimer

The Isolation Calculator 60601-1 can help to determine the correct air and creepage distances including the necessary test voltages. It can not check if the input values make sense for a certain medical device. The Isolation Calculator 60601-1 is provided as is without warranty of any kind. The author Arno Morbach disclaims all implied warranties.

The program has been thoroughly verified but the author can not be made responsible in any way if an inspection authority requires other values.

Consult the IEC 60601-1 and / or notified bodies for all design decisions.

The entire risk arising out of the use or performance of this tool and its documentation remains with the user.

In no event shall Arno Morbach be liable for any damages whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, or other pecuniary loss) arising out of the use of or inability to use the Isolation Calculator, even if Arno Morbach has been advised of the possibility of such damages.