Bio-Medical Engineering Technical Standard: BETS-0716-1

Electrical Safety Testing of Medical Devices: July 2016

FORWARD:

Medical Devices are designed and rigorously tested to IEC60601 group of standards in a certified laboratory. This extensive Type testing, sometimes to the point of destruction is carried out prior to the medical device being released for sale.

In Australia, the results of the tests are submitted to Therapeutic Goods Administration and when approved, the medical devices can be sold here.

Standards Australia have failed to provide a clear on-going Electrical Safety Testing regime for medical devices with the release of AS/NZS3551:2012 as Appendix B of the standard contained omissions, incorrect interpretations of international standards and added tests that would not in any way show additional electrical hazards that were already covered in AS/NZS3551:2004.

This Bio-Medical Engineering Technical Standard has been produced to provide a true Field Testing regime that reduces the tests to a minimum but still maintains high levels of electrical safety.

The tests listed are accompanied with explanatory notes to clarify the objectives of the tests.

TESTING REGIME, CLASS I DEVICES, No Applied Parts:

Tests are to be performed in the following order.

1. Ground Wire Resistance (GWR)

2. Insulation Resistance

3. Touch Current/Earth Leakage Neutral Open

4. Earth Leakage Current Neutral Closed.

TESTING REGIME, CLASS I DEVICES, Type B Applied Parts:

Tests are to be performed in the following order.

1. Ground Wire Resistance (GWR)

2. Insulation Resistance

3. Touch Current/Earth Leakage Neutral Open

4. Applied Part Current Neutral Open

5. Earth Leakage Current Neutral Closed.

6. Applied Part Current Normal

7. Applied Part Current Earth Open

TESTING REGIME, CLASS I DEVICES, Type BF Applied Parts:

Tests are to be performed in the following order.

1. Ground Wire Resistance (GWR)

2. Insulation Resistance

3. Touch Current/Earth Leakage Neutral Open

4. Applied Part Current Neutral Open

5. Earth Leakage Current Neutral Closed.

6. Applied Part Current Normal

7. Applied Part Current Earth Open

8. Mains Contact Current BF Normal

TESTING REGIME, CLASS I DEVICES, Type CF Applied Parts:

Tests are to be performed in the following order.

1. Ground Wire Resistance (GWR)

2. Insulation Resistance

3. Touch Current/Earth Leakage Neutral Open

4. Applied Part Current Neutral Open

5. Earth Leakage Current Neutral Closed.

6. Applied Part Current Normal

7. Applied Part Current Earth Open

8. Mains Contact Current CF Normal

TESTING REGIME, CLASS II DEVICES:

1. Insulation Resistance

2. Touch Current Neutral Open

3. Touch Current Neutral Closed.

GROUND WIRE RESISTANCE:

Discussion: There are a few points to make here. In Australia we have high standard electrical reticulation before the power is presented to our medical treatment facilities. Then on top of that we have the additional level of safety provided by AS/NZS3003 that has special wiring in high risk Cardiac Procedure Areas and now calls for all patient treatment locations to provide power via a Residual Current Device or Isolation Transformer. Internationally when an RCD is provided the GWR can be relaxed to 0.5Ω.

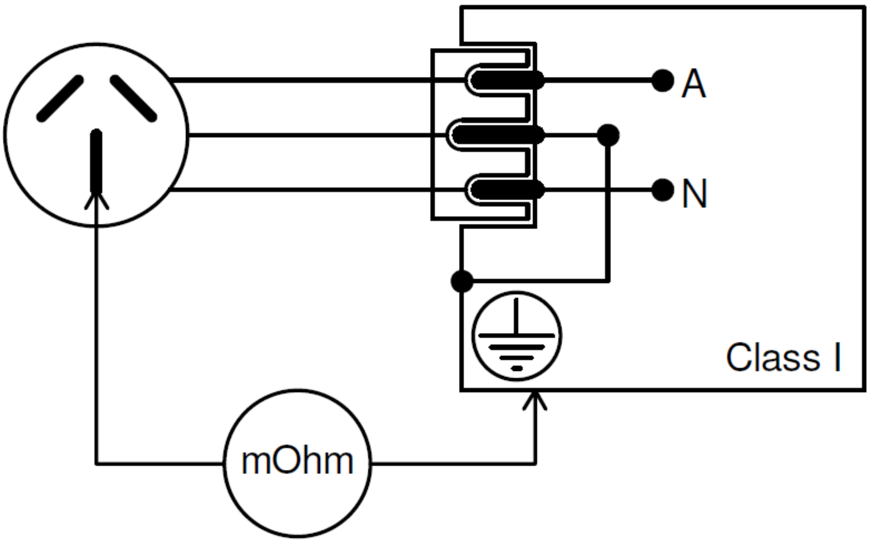
An overlooked problem with leads is power dissipation. When all connections have been correctly terminated the resistance in the earth line is the same resistance as in the two current carrying conductors.

In the above with relaxation to 0.5Ω , the lead used with a low current device is not an issue. But if the same lead is then used on a high current device such as 10Amps, you have 10 x 10 x 0.5 = 50 Watts of power per line. Experience has shown that the resistance of the removable leads is not localized to the plug top, the lead itself but quite often is focused on the moulded IEC end and this causes the melting of these connectors at this point and has the potential to start fires.

The Ground Wire Resistance (GWR) measurement is made from a point on the protectively earthed case of a Class I device through to the Earth pin on the plug top. For fixed wired devices the limit is 0.2Ω and for removable leads 0.3Ω.

The accuracy for the measurement is +/- 3%.

In the case of removable leads, if the measurement is outside of this limit, then the lead should be removed; the contact earth point of the device to the protectively earthed case confirmed to be no greater than 0.1Ω; and then the lead tested separately as well.

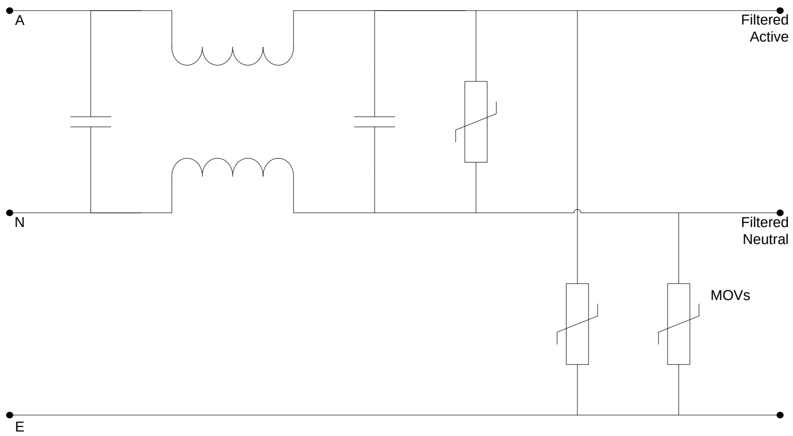


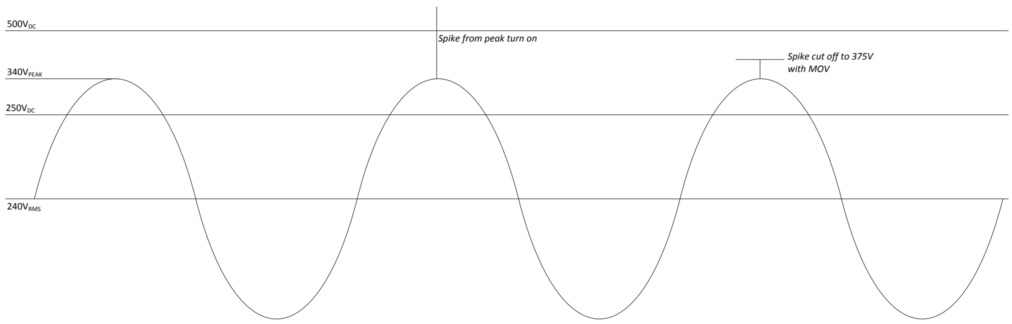
INSULATION RESISTANCE:

Discussion: Insulation Resistance testing is to ensure that there is not an insulation breakdown between the current carrying conductors and earth. Testing over a number of years showing this level dropping can indicate potential failure and the device can be removed from service and repaired before major damage takes place.

Solid state devices used for switch mode power supplies fed from mains power can be subjected to large transient spikes that could damage them. To protect them Metal Oxide Varistors, MOVs, or Transient Voltage Suppressors, TVSs, can be fitted. In Australia our 240V rms lines actually peak at 340V and an inductive load at this peak will produce a large transient spike. The MOVs & TVSs quickly conduct around 375V and cut off any levels above that point. Applying an Ins Res test at 500V will make the protection devices conduct and

give a low Ins Res reading. By repeating the test at 250V we come below the 375 volt conduction level and healthy readings would be expected. MOVs suitable for 240V mains are rated as 275LA10 for example with 275 the RMS level and 10 being the energy absorption level.



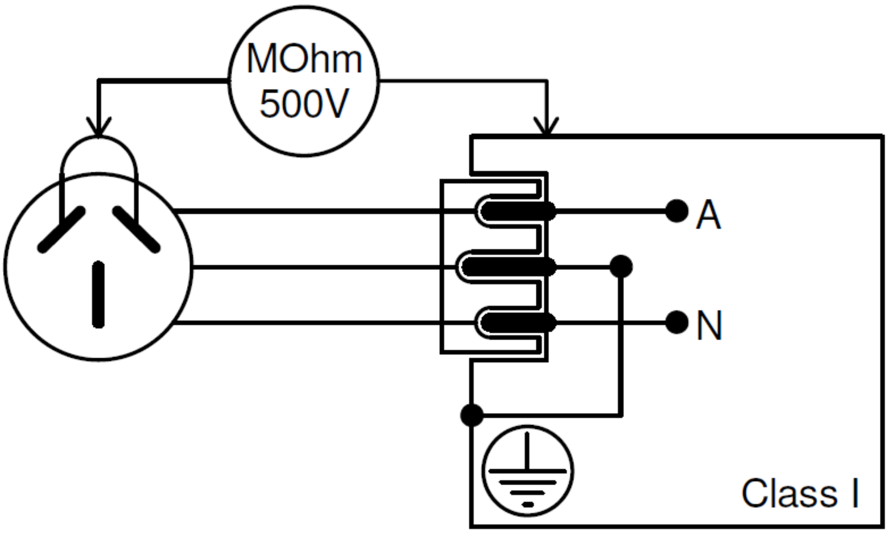


Insulation Resistance is measured from the Active and Neutral conductors shorted together across to the earth conductor.

The test is normally applied at 500V DC and for devices fitted with MOVs or TVSs the voltage can be reduced to 250V DC. (See discussion.)

The 500V source can have a tolerance of not less than 500V but not greater than 650V and for 250V, not less than 250V and not greater than 325V.

The accuracy of the measurement is +/-5% at 10MΩ.

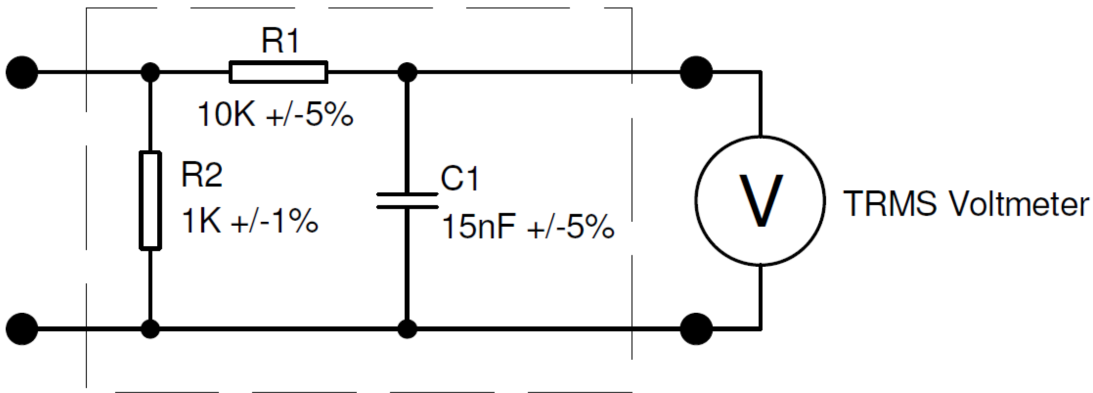


TOUCH CURRENT/EARTH LEAKAGE CURRENT

Discussion: Before any Touch Current/Earth Leakage Current measurements are made, correct polarity of the mains supply must be guaranteed as opening up the Active rather than the Neutral will give incorrect measurements.

Research with International standards and consultation with a UK Biomedical Consultant has resulted in the fact that Touch Current is only measured by touching the Measuring Device, MD, to a NON PROTECTIVELY EARTHED CONDUCTIVE SURFACE and measuring between this point and ground.

The Measuring Device, MD, consists of the 1K, 10K, 0.015uF roll off filter connected to a DC coupled TRMS meter and has an accuracy requirement of +/-5%.



Touching the protectively earthed case of a Class I device and opening up the earth return line via the lead will mean that the TOUCH CURRENT IS EARTH LEAKAGE CURRENT. Touching the protectively earthed case with the earth line intact is a waste of time as the current will always be close to zero as you have the 1KΩ MD in parallel with a maximum of 0.3Ω.

Class II devices will be discussed later. The BME Eng/Tech has to decide which medical devices have NON PROTECTIVELY EARTHED CONDUCTIVE SURFACES, whether they are suitably isolated from design and construction or that with use/wear and tear they should be included in the regular testing regime.

It is also recommended that for Class I devices, Touch Current testing is carried out with the Neutral Open because with all Leakage Current Tests, this will give the highest reading.

By doing all of the Neutral Open current tests first, the medical device is not powered up and down that may affect the start-up procedure for what is often very expensive and technically sophisticated medical equipment.

TOUCH CURRENT TEST: Connect the MD between the NON PROTECTIVELY EARTHED CONDUCTIVE surface and ground with Neutral Open.

Pass/Fail Threshold for Touch Current: 500uA.

EARTH LEAKAGE CURRENT TEST: Connect the MD in series with the return earth line of the medical device. (Ensure medical device has no other return earths.)

Pass/Fail Threshold for Leakage Current, Neutral Open, 1000uA.

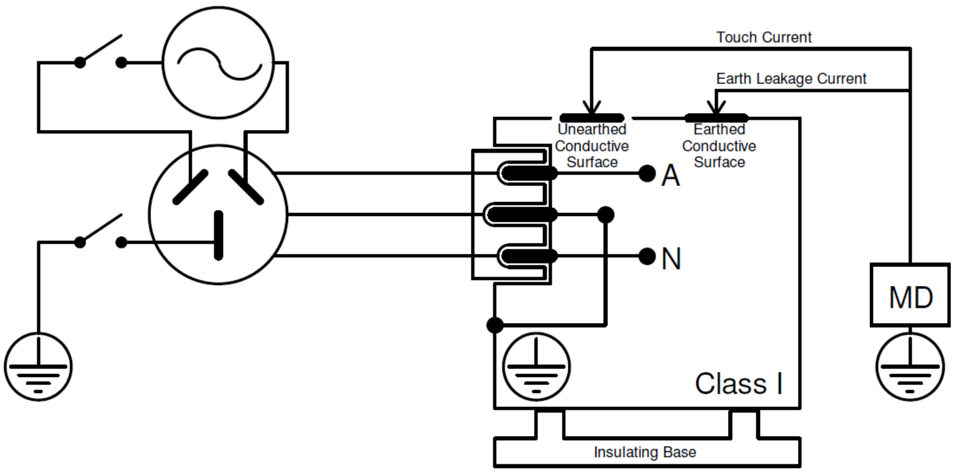
Pass/Fail Threshold for Leakage Current, Normal, 500uA.

Pass/Fail Threshold for Leakage Current for X-Ray equipment:

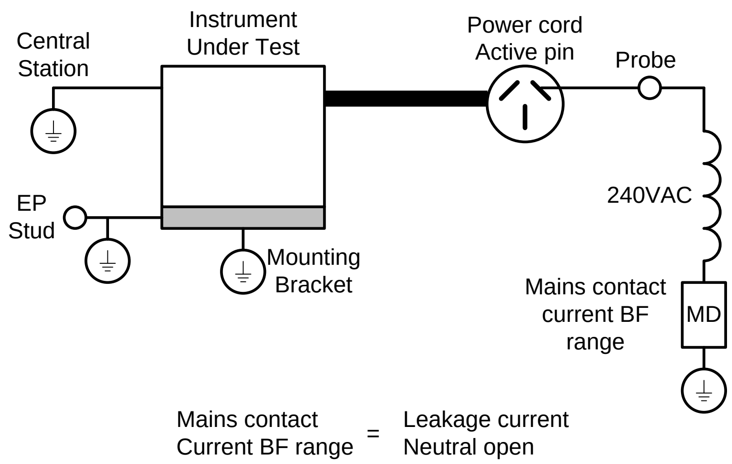
Neutral Open, 5000uA, Neutral Closed, 2500uA.

Pass/Fail Threshold for Leakage Current for permanently wired equipment:

Neutral Open, 10000uA, Neutral Closed 5000uA.



PSEUDO EARTH LEAKAGE CURRENT TEST.



MEMIE Figure

The ***MEMIE Figure*** shows the Mains Contact Current Test, set on the BF range applied to the active pin of the equipment power cord.

The instrument under test has multiple earth connections and therefore the conventional earth leakage test set up will not provide accurate readings.

The pseudo earth leakage current test will give an approximation of the worst case - neutral open earth leakage current without the need to disconnect all of the earths.

CLASS II DEVICE TESTING:

Discussion: Class II or Double Insulated devices normally are a two wire powered device without an earth return wire. If the device contains an earth return wire, this is normally to provide a functional earth for internal filtering devices and the leakage current flowing down the earth wire will have the same limits as a Class I device.

Being Double Insulated, the case has no protective earth surround so to test for leakage current coming from the device, aluminium foil is wrapped around the case or for large devices around the area of the mains power section/entry or obvious entry points into the device. (Like the chuck of a drill, AV connections of a television to give you the idea.)

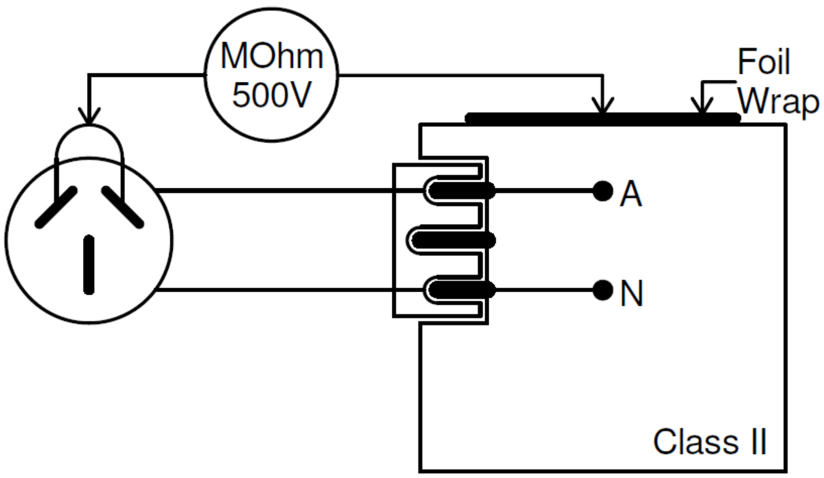
Insulation Resistance is measured between the Active/Neutral and the foil/contact point and then Leakage current measurements are also made to the same points.

Leakage Current from a Class II device was correctly named enclosure leakage and now in later standards as the new name for Enclosure Leakage is Touch Current then Class II tests are rightly named Touch Current Tests. This is true Touch Current Testing and you would apply this test to any conductive surface on the Class II device.

Insulation Resistance Pass/Fail Threshold A/N to contact point 1.0MΩ

Touch Current Pass/Fail Threshold Neutral Closed, 500uA.

Touch Current Pass/Fail Threshold Neutral Open, 1000uA.



APPLIED PART CURRENT TESTING:

Discussion: Applied Part Current Testing should be viewed as current that can be SOURCED from the Applied Parts. By connecting the MD between the Applied Parts and Ground, it makes sense that as the Active, Neutral & Earth conductors coming into the device may have pathways or capacitive coupling to the Applied Parts and hence three tests should be made. Supply conductors normal, Neutral Open & Earth Open.

Type B Applied Parts:

Pass/Fail Threshold for Applied Part Current, Normal, 100uA

Pass/Fail Threshold for Applied Part Current, Neutral Open, 500uA

Pass/Fail Threshold for Applied Part Current, Earth Open, 500uA

Type BF Applied Parts:

Pass/Fail Threshold for Applied Part Current, Normal, 100uA

Pass/Fail Threshold for Applied Part Current, Neutral Open, 500uA

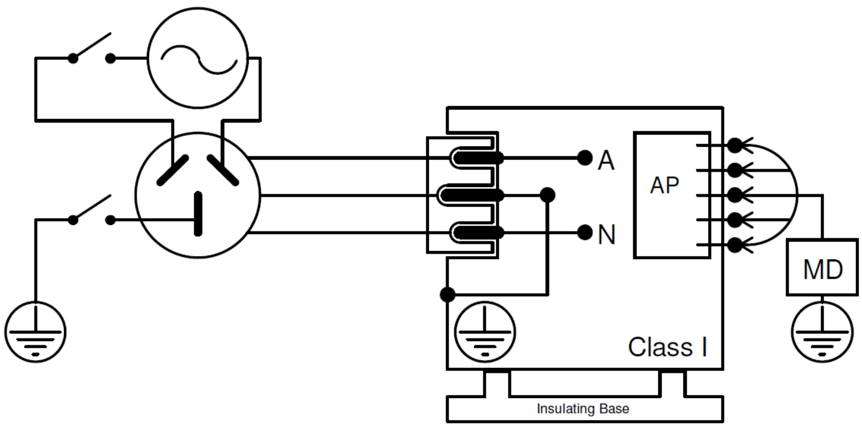
Pass/Fail Threshold for Applied Part Current, Earth Open, 500uA

Type CF Applied Parts:

Pass/Fail Threshold for Applied Part Current, Normal, 10uA

Pass/Fail Threshold for Applied Part Current, Neutral Open, 50uA

Pass/Fail Threshold for Applied Part Current, Earth Open, 50uA



MAINS CONTACT CURRENT TESTING:

Discussion: Mains Contact Current Testing should be viewed as current that can be SINKED INTO the Applied Parts. By connecting the MD between Ground a small transformer generating an isolated mains voltage and then connecting the other side of the transformer to the Applied Parts, it makes sense that as the Active, Neutral & Earth conductors coming into the device may have pathways or capacitive coupling to the Applied Parts the worst case or highest reading would result when the Supply Conductors are Normal. One only test is therefore required. Neutral Open, Earth Open tests are a waste of time. Type CF Applied Parts can now be done with all Applied Parts joined together.

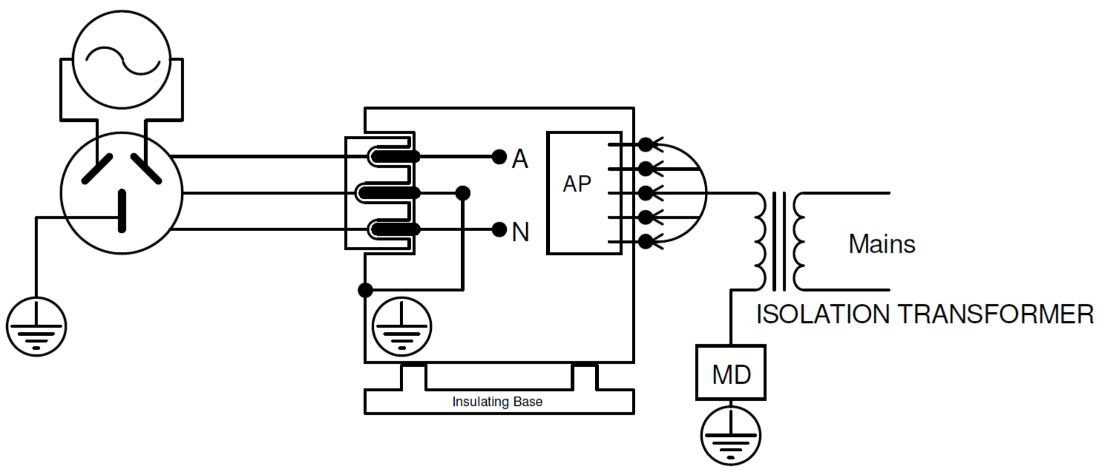
Transformer Specifications: Mains Voltage Primary = Mains Voltage Secondary +/- 5% with full BF fail point of 5mA load applied.

Type BF Applied Parts:

Pass/Fail Threshold for Mains Contact Current, Normal, 5000uA.

Type CF Applied Parts:

Pass/Fail Threshold for Mains Contact Current, Normal, 50uA.



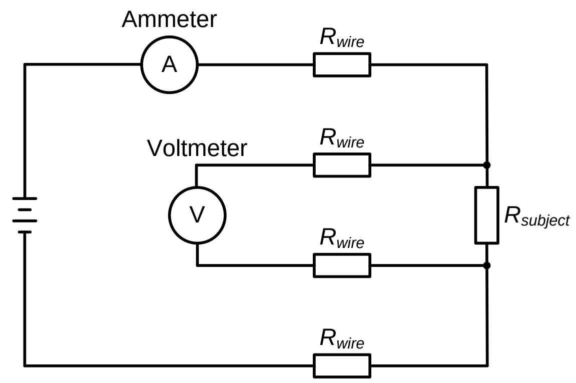
TESTING REGIME: All visual inspection and testing regimes are based on the experience of the Bio-Medical Engineer. Medical Devices may be subject to physical abuse and extremes of temperature prior to being delivered to the hospital/ medical facility and therefore should undergo a full testing regime. Similar full testing is applied following service to the medical device. When in

service the testing regime should reflect on the usage of the device, wear and tear from regular transport or movement, wet areas etc. It is generally accepted that no In-Service Applied Part or Mains Contact Current Tests are required for equipment that is for example shelf mounted and never moved.

TESTING LOW OHMS IN A CARDIAC PROTECTED AREA:

The 4 wire Kelvin Technique is the most used method for measuring the low milliohm requirements for the earth reticulation in and around Cardiac Protected Areas. The theory is explained below.

KELVIN 4-wire Technique



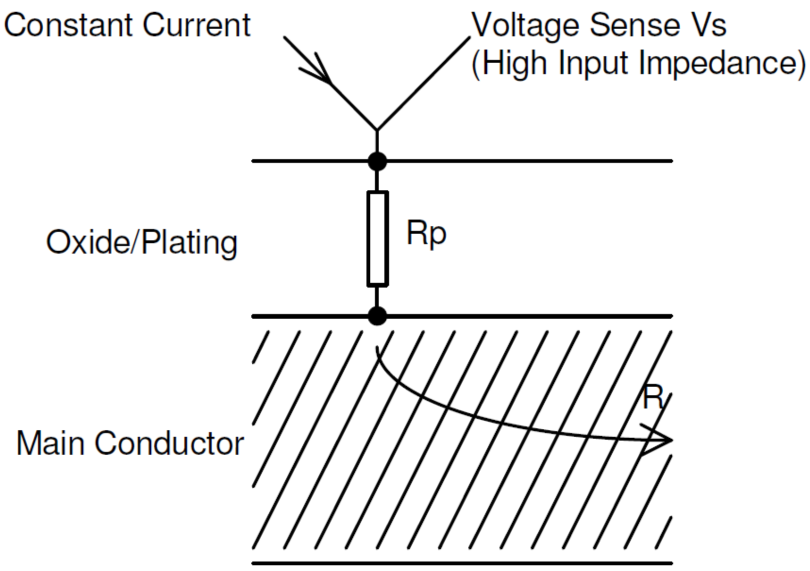
$$R_{subject} = \frac{\text{Voltmeter indication}}{\text{Ammeter indication}}$$

After studying the above diagram, take out the Ammeter and substitute a constant current generator that is set to 1.00 Ampere. The voltmeter has a high input impedance so the R wire resistance in the voltmeter lines can be ignored and as we have a constant current so too can the R wire resistances in the current lines. Hence the Reading on the Voltmeter = 1 x R or the voltmeter reading is the resistance reading.

Using this technique when measuring low Ohms in a Cardiac Protected Area with 2 x 10 metre leads you can still have an accuracy of +/- 0.001 ohm.

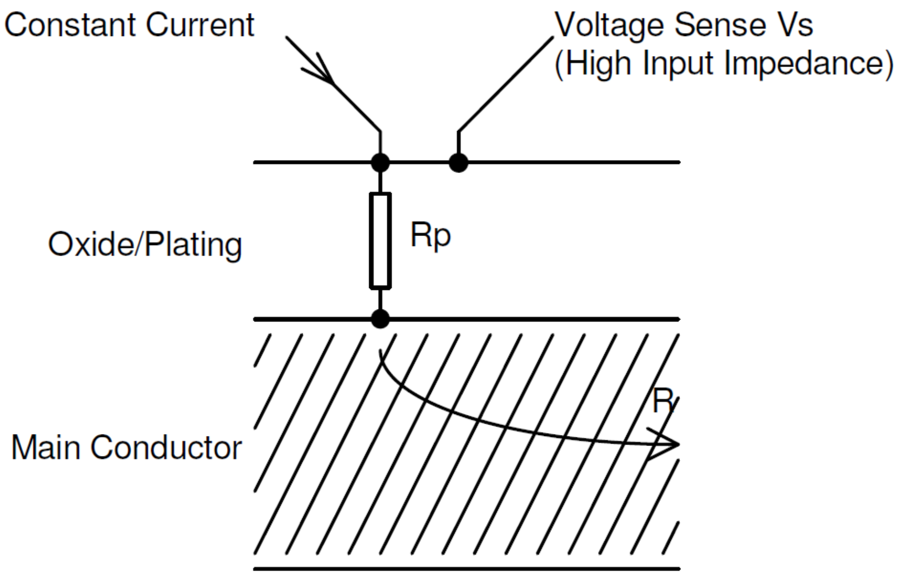
OXIDIZED & PLATED SURFACES:

When measuring very low milliohms, oxidation may give false readings. Lawrie Knuckey first came up with the idea to separate the sense and current wires to overcome the added small resistance and get the baseline reading. This is explained below.



Vs = (Ik x Rp) + (Ik x R)

Here the measurement includes the oxidation/plating resistance.



Vs = Ik x R

As discussed before, by separating the current from the sense contact points the high input impedance of the sense voltmeter ignores the oxidation/plating resistance and gives you the more accurate main resistance value.

ACKNOWLEDGEMENTS:

With 50 years of working in the Bio-Medical Engineering field fast approaching it is only fitting that I acknowledge those who passed on their knowledge and have also constructively commented on the preparation of this document.

Lawrie Knuckey, John Southwell, Jack Davie, Peter Ampt, Robert Di Pierro & Simon Cowley.

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Justin McCarthy, Comments on leakage current testing of medical electrical equipment.

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Justin is also Chairman of SC 62A Common aspects of electrical equipment used in medical practice.

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