



RIGEL MEDICAL

GMC-INSTRUMENTS GROUP

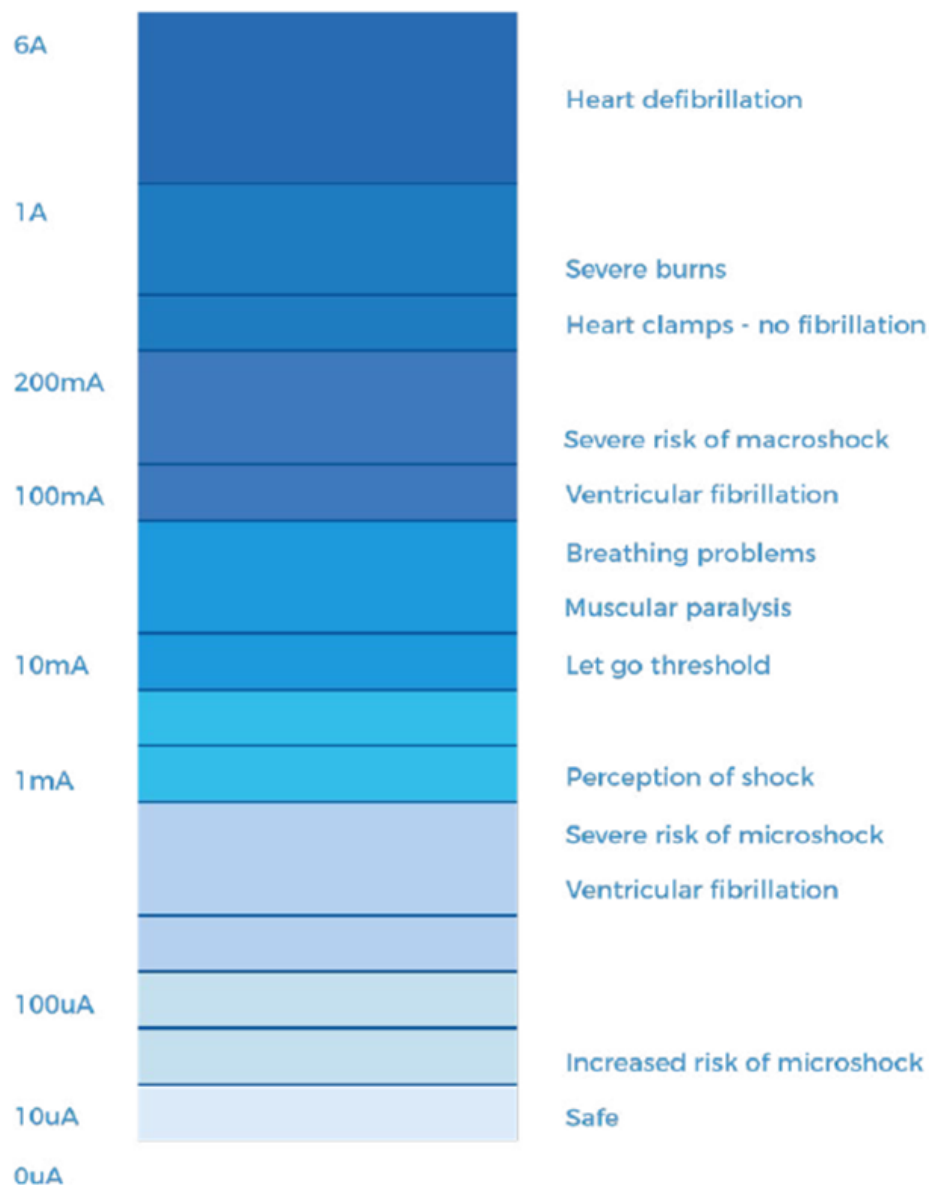
What is the difference between Macroshock and Microshock?

There are two distinct types of electrocution which need to be considered in healthcare environments: macro-shock and micro-shock.

Macro-shock occurs when current passes through the body via contact with the skin and this aspect applies to all types of electrical safety. However, external dry skin has high resistance, which limits current flow through the body. Many medical procedures involve moistening the skin, which lowers skin resistance significantly, such as ultrasound gel and surgical applicants. Furthermore, patients are often in constant physical contact with medical electrical (ME) equipment, both directly and indirectly e.g., electrical monitoring systems and electrically powered beds. The results from macro-shock lead to loss of voluntary muscle control at currents as low as 10mA and ventricular fibrillation at currents of approximately 100mA.

| Physiological Effect | Gender | DC | 60Hz AC | 10 kHz |
|--|--------|--------|---------|--------|
| Slight sensation | Men | 1 mA | 0.4 mA | 7 mA |
| | Women | 0.6 mA | 0.3 mA | 5 mA |
| Threshold of perception | Men | 5.2 mA | 1.1 mA | 12 mA |
| | Women | 3.5 mA | 0.7 mA | 8 mA |
| Pain, voluntary muscle control "Let-go" | Men | 62 mA | 9 mA | 55 mA |
| | Women | 41 mA | 6 mA | 37 mA |
| Pain, involuntary muscle control | Men | 76 mA | 16 mA | 75 mA |
| | Women | 51 mA | 10.5 mA | 50 mA |
| Severe pain, difficulty breathing, 99.5% percentile muscle control lost | Men | 90 mA | 23 mA | 94 mA |
| | Women | 60 mA | 15 mA | 63 mA |
| Ventricular fibrillation (3 seconds) | Men | 500 mA | 100 mA | |
| | Women | 500 mA | 100 mA | |

Micro-shocks occur when invasive patient connections are placed across or in close proximity to myocardial tissue and nerves and blood components have relatively low resistance. Therefore, very small levels of electrical current can induce ventricular fibrillation because tissue impedance below the skin surface is low and current is focussed at an invasive location. Death by micro-shock is known as micro-electrocution and both catheters and pacemakers carry this risk. It has been repeatedly estimated that currents of over 20 microamps can lead to micro-electrocution. Patients in medical environments are uniquely vulnerable to the risks from micro-shock.



Several corresponding studies have recognised the physiological effects of electrical current under macro-shock and micro-shock conditions, and international standards reflect these results in their safety criteria. In 1971 “Ralph Nader’s Most Shocking Exposé,” revealed that about 1,200 people a year were dying in hospitals from the effects of micro-shock. Several years later, in 1977, the safety standard IEC 60601 was formed and parts of it have survived to this day. Further developments and revisions have led to year on year reductions in death from both macro and micro-electrocution.

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