Guidelines For Clinical Engineering Programs

Part III: The Risk Of Electrical Shock In Hospitals

Part IV: Isolated Power In Anesthetizing Locations? History Of An Appeal

MALCOLM RIDGWAY, Ph.D., C.C.E.
Director, Shared Biomedical Engineering Service
Council Shared Services*
Van Nuys, California

This four-part series presents guidelines for: electrically isolated inputs and outputs; measuring the performance of hospital biomedical engineering programs; evaluating the risk of electric shock in hospitals; and for isolated power in anesthetizing locations. Parts I and II, covering the first two topics above, were published in the Oct.-Dec. 1980 issue of this Journal.

Part III constitutes an attempt to place the risk of electric shock in hospitals in a quantitative perspective. Arguments are presented that indicate that electrical safety precautions usually take up a larger share of the hospital’s biomedical equipment safety budget than is justified by the actual hazard levels.

Part IV reviews the need for isolated power in anesthetizing locations. Three independently proposed revisions to the 1973 edition of NFPA Standard 56A would have significantly simplified the safety requirements for hospital anesthetizing locations (a) by reducing the area in flammable locations classified as hazardous to the internationally accepted “zone of risk,” and (b) by permitting the use of conventional electrical power rather than isolated power in locations where the risk of electrical accidents can be shown to be no greater than it is in other areas of the hospital. Despite extensive technical testimony supported with substantial supporting documentation, the revisions were vetoed by the Technical Committee after they were voted into the document by a floor vote of the general membership attending the NFPA Annual Meeting in Anaheim in 1978. The chronology of the major events surrounding the subsequent appeal of this veto is traced back to 1974, and an analysis is presented of what are considered to be shortcomings in the NFPA appeals process revealed by this particular case history.

Key Words: Electrical Safety; Isolated Power; In-House Service Programs; Electrical Shock; Guidelines, Clinical Engineering Programs; Isolated Inputs; Patient Safety; Surgical Suites; Flammable Gases Safety; Standards, Electrical Safety.

PART III: THE RISK OF ELECTRIC SHOCK IN HOSPITALS

It is time to attempt to put concern about the risk of electric shock in hospitals into some kind of convincing quantitative perspective. In spite of the findings to the contrary published by several authoritative researchers, ten years of discussion about electrical safety hazards has created an apparently unshakeable impression that electrical safety in hospitals requires much more heroic measures than electrical safety in other places. Honest, commonsense analyses of various hospital settings indicate that, compared to other device-related problem areas that merit the attention of the biomedical staff, electrical safety measures are still given too much attention and too large a share of the hospital’s biomedical resources — probably to the overall detriment of optimum patient safety.

NOTICE: The opinions presented in this article are those of its author and are not necessarily those of this Journal, Quest Publishing Co., the Editor, Publisher or Staff.

*Reprinted, with permission, from Biomedical Engineering Guideline Reports 78-09 & 79-20, Shared Biomedical Engineering Service, Council Shared Services (Council Shared Services is a division of the Hospital Council of Southern California), Van Nuys, California.
As we see it, a large part of the problem is that the various technical groups that have been charged with making electrical safety standards or design recommendations seem to have developed tunnel vision and themselves become vested-interest advocates of unnecessarily stringent electrical safety measures. Although they would seem to be in the best position to do so, they have not attempted to provide any estimates of the level of risk encountered in typical hospital situations or any guidelines on the extent to which the recommended safety measures will reduce those levels of risk. We feel that the development of a simple "electrical safety rationale" is long overdue, particularly since such a step would go a long way towards eliminating any acrimonious, non-scientific debate.

THE "LAYERS-OF-PROTECTION" CONCEPT

Since electric shock results from the effect of an electric current flowing through a part of the human body, three conditions must be satisfied simultaneously before a patient (or anyone else for that matter) can be shocked. There must be:

- one part of the body in contact with a conductive surface (Fig. One a);
- a different part of the same body in contact with a second conductive surface (Fig. One b);
- and a voltage source that will drive current through the body between those two points of contact (Fig. One c).

In the general case, six or seven independent and separable factors must combine simultaneously to satisfy these three conditions. The probability of the patient actually sustaining an electric shock is the product of the associated six or seven separate probabilities. (Fig. Two) If any one of those component probabilities is very close to zero, or can be reduced to a level that is very close to zero, the risk is likewise reduced to very close to zero. Because we seem to distrust statistically-based estimates, it is usually considered prudent not to depend completely on one safety factor, even though it may appear to offer a very high level of reliable protection. A second so-called "layer of protection" is obtained by arranging to make the probability of a second factor in the overall equation also very close to zero. Extending this process indiscriminately however, obviously leads to overdesign or overspecification. Once a quantitative goal has been set for what is considered to be a reasonably small risk level, a little commonsense analysis will reveal which factors should be used to provide the primary safeguards.

![Figure 1](image1.png)

\textit{Figure 1}
\textit{The Three Basic Conditions Required To Produce An Electric Shock.}

![Figure 2](image2.png)

\textit{Figure 2}
\textit{Several Separate Factors Must Be Analyzed When Evaluating A Potential Electric Shock Hazard.}
General Factors That Must Be Considered
When Analyzing Electrical Safety

(1) the likelihood that a piece of line-powered equipment will be within reach of the patient;

(2) the possibility of direct exposure to a "live" 120V conductor through a damaged line cord or attachment plug;

(3) the likelihood that the equipment will have exposed metal parts that, through some reasonably credible accident, could become "live;"

(4) the likelihood that equipment is accidentally damaged or malfunctions in some way and the metal becomes "live" i.e., electrified;

(5) the likelihood of the exposed metal parts not being grounded or accidentally becoming ungrounded;

(6) the likelihood that the patient (or member of staff, or visitor) will make good contact with this exposed, potentially "live" surface;

(7) the likelihood that a second exposed conductive surface that is, or which could, through a reasonably credible event, become grounded, is also within reach;

(8) the likelihood that the patient (or member of staff, or visitor) will make good contact with this grounded, or potentially grounded, surface; or

(9) the probability that the resultant current flow will be sufficient to cause an injury.

According to the recently published results of a carefully controlled study ("Report on the Medical Insurance Feasibility Study" edited by D. H. Mills. Sutter Publications, Inc., [1977]) made of the hazards associated with a stay in a typical California hospital, the risk of accidental death per year, while a hospital patient, is surprisingly high — about 6800 x 10^-7. By way of comparison, information drawn from accident statistics (some of which are shown in the table below) shows the general public willing to consider acceptable risk levels of about 10 x 10^-7 for natural disasters and about 1 x 10^-7 for man-made disasters.

If all levels of adverse outcomes from events taking place during hospitalization are considered (from death down to minor temporary disabilities), the risk level increases to 70,000 x 10^-7, of which, (according to the study), 4.1% of the incidents are associated with the use or misuse of an item of medical equipment. By interpretation, the risk of dying from an equipment-related incident in hospital, is therefore, about 280 x 10^-7 (about 1000 incidents per year).

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>RISK OF DEATH</th>
</tr>
</thead>
<tbody>
<tr>
<td>motor cycling</td>
<td>20,000 x 10^-7</td>
</tr>
<tr>
<td>auto racing</td>
<td>14,000 x 10^-7</td>
</tr>
<tr>
<td>driving auto</td>
<td>1,700 x 10^-7</td>
</tr>
<tr>
<td>rock climbing</td>
<td>1,400 x 10^-7</td>
</tr>
<tr>
<td>flooding</td>
<td>22 x 10^-7</td>
</tr>
<tr>
<td>lightning storm</td>
<td>8 x 10^-7</td>
</tr>
<tr>
<td>struck by part of falling aircraft</td>
<td>1 x 10^-7</td>
</tr>
<tr>
<td>struck by meteorite</td>
<td>0.0006 x 10^-7</td>
</tr>
</tbody>
</table>

The Risk Of Accidental Death Associated With Several Common Activities And Several Natural Hazards

ILLUSTRATIVE ANALYSIS OF THE RISK OF ELECTRICAL "MACROSHOCK"

Because of the proliferating use of electrically-powered devices in today's hospitals, patients and members of the hospital staff are more frequently exposed to the risk of electric shock from a damaged or malfunctioning device. The following analysis is provided to illustrate how actual risk levels can be estimated and how the analysis can be used to develop appropriate strategies, regarding which factors can be best used to provide the desired number of layers of protection. The probability associated with each individual factor will be designated P_i, as follows:

P_1. Assume that there is an 80% probability that at least one piece of line-powered equipment will be within reach of the patient. 

\[ P_1 = 0.8 \]
P2. Assume that there is a 95% probability that the equipment will have exposed metal parts that could become "live" through some reasonably credible accident. ................. 0.95

P3. Assume that the probability that the equipment is accidentally damaged and the exposed metal becomes "live" (and the condition is neither noticed nor corrected) is 1 in 1000 .......... 10^{-3}

P4. Assume that the probability that the exposed metal is either not grounded (contrary to good practice) or that it becomes accidentally ungrounded, is 1% .................. 10^{-2}

P5. Assume that the probability that the patient will reach out and touch the exposed metal surface of the equipment is 1% .................. 10^{-2}

P6. Assume that the probability that there is a second exposed and grounded conductive surface also within reach of the patient is 80% .................. 0.8

P7. Assume that the probability that the patient will reach out and make good contact with the grounded surface is 10% .................. 0.1

P8. Assume that current passes from hand-to-hand through the patient (worst case) and that the volume impedance of the body tissue along this pathway is about 4,000 ohms (typical, provided that the skin is not saturated or broken) then a current of about 27.5 milliamps will pass. The probability that a current of this magnitude will be fatal is about 30% .............. 0.3

The combined probability of a fatal incident involving a hospital patient is, therefore 1.82 \times 10^{-9}. Since about 37 million patients are admitted into hospitals each year, the estimated probability of being admitted to the hospital is 0.185 and the risk of accidental death from "macroshock" electrocution while a patient in a hospital is, therefore... 3.4 \times 10^{-10} or 0.0034 \times 10^{-7}.

This estimated level of risk would lead us to expect about 0.067 incidents of macroshocked patients per year (or about one incident every 15 years). The actual reported incident level is somewhat larger than the estimate that the analysis leads us to, which suggests that we underestimated at least one of the component probabilities or that many of the reported incidents arise from the probability that we did not consider, e.g., the directly exposed conductor in a damaged line cord or attachment plug.

DISCUSSION

Consider briefly, each of the component factors. First, more could be done to ensure that the minimum amount of line-powered equipment is within reach of the patient. Second, equipment that does not have a significant amount of exposed metal is to be preferred. Third, the staff should be instructed to report all obviously damaged equipment, even if it is still functional. Fourth, all grounding circuits should be tested frequently. Fifth, minimize the amount of grounded metal that is within reach of the patient. Do not attach any grounded leads directly to the patient. Do not deliberately ground any metal part such as a curtain rail or a metal cabinet which cannot become accidentally "live." Insulate the patient from ground as much as possible.

Although we did not analyze a typical situation involving a member of the hospital staff, they are probably more at risk with respect to macroshock than the patient. High risk areas include the kitchen, where there is frequently a hazardous combination of damaged or poorly maintained electrical equipment and grounded plumbing around sinks; the clinical laboratory, where there is often electrically-powered equipment in close proximity to grounded surfaces (plumbing, etc.); hydrotherapy areas, where there is often a combination of electrical equipment, grounded surfaces and a wet environment; and the equipment repair shop, where technicians must work on defective electrical equipment. In these particular locations, where several of the component factor probabilities cannot be controlled, consideration should be given to using special safeguards, such as ground fault circuit interrupters (GFCI) or isolated power systems (IPS), to provide an additional layer of protection.

The conductive floor of an anesthetizing location does not provide a significant macroshock hazard because it is specially designed to provide a resistance to ground which will limit the current that can flow through the body, (even from a direct contact with 120 volts), to a sublethal level. Because of this, the argument, that isolated power is needed to provide a reasonable level of protection against macroshock, is no more valid in the typical OR than it is at several other locations in the hospital, such as the equipment maintenance shop.
The rationale for leakage current standards can also be evaluated using this type of analysis. In the case of patient leads and other conductors associated with line-powered equipment that are deliberately connected to the patient, the layers of protection identified above as $p_1$, $p_2$, $p_3$, $p_4$, and $p_5$ are lost. Thus, the amount of leakage current that is permitted, and which would flow to ground if the patient touched a grounded surface, should probably be limited to an intrinsically safe value; that is, one which would not injure the patient in any way. For currents substantially below the physiological threshold of perception, (200-500 microamps), the associated probability ($p_8$) becomes zero. The generally accepted standard in the U.S. for patient-lead leakage is 50 microamps. This represents a conservative standard since in the general case the product of the probabilities associated with the two other layers of protection ($p_6$ and $p_7$) is also a relatively small value (about 0.08).

The value which is being advocated by AAMI and others as the U.S. standard for ground lead leakage (100 microamps) is even more conservative, since in the general case where this current becomes a shock hazard, only one of the layers of protection discussed above ($p_3$) is lost, and there is therefore, a much smaller justification for requiring that the current level be set well below the intrinsically safe value. The international standard set by the International Electrotechnical Commission (IEC) gives consideration to the many other layers of protection which are present and which themselves reduce the risk to a very small level. The IEC sets the ground lead leakage current standard at 500 microamps.

**ILLUSTRATIVE ANALYSIS OF THE RISK OF "MICROSHOCK."**

A patient, fitted with either temporary pacemaker leads or with some other type of conductive pathway directly to the inner wall of the ventricle, is theoretically susceptible to electrically-induced ventricular fibrillation.

Ignoring, for the moment, the case of a defective device connected directly to the conductive pathway, at least eight factors must combine in order to "microshock" this patient. Again, this particular analysis is intended to illustrate how the actual risk levels can be estimated and strategies for providing additional protection evaluated:

**P1. Assume that there is a 99% probability that at least one item of line-powered equipment will be within reach of the patient or his attendants.**

**P2. Assume that there is a 95% probability that the equipment will have exposed metal parts that could become "live" through a reasonably credible accident.**

**P3. Assume that the probability that (either through poor design or malfunction) the device has 250 microamps of leakage current flowing at the chassis is 10%**

**P4. Assume that the probability that the equipment has become accidentally ungrounded is 1%**

**P5. Assume that the probability that, contrary to good practice, the pacemaker's lead is unprotected and a member of the staff simultaneously touches the exposed, ungrounded surface, and the exposed end of the pacemaker lead is 0.1%**

**P6. Assume that the probability that there is a second exposed and grounded conductive surface also within reach of the patient is 80%**

**P7. Assume that the probability that the patient will make good contact with the grounded surface is 10%**

**P8. Assume that the tip of the conductive lead makes direct contact with the inner wall of the ventricle (worst case).**

According to published research reports, the probability that the 250 microamp current will cause the heart to fibrillate is 60%.

The combined probability of the patient being microshocked in a manner corresponding to this analysis is $4.5 \times 10^{-8}$. If we assume that 5% of all patients are catheterized each year (1.85M), the probability of being catheterized is about $0.925 \times 10^{-2}$ and the estimated risk of being fatally "microshocked" while a patient in hospital is, therefore, $4.16 \times 10^{-10}$ or $0.0042 \times 10^{-7}$.

**DISCUSSION**

This estimated level of risk would lead us to expect about 0.083 incidents of fatal microshock per year (or about one incident every 12 years.) The failure to uncover any substantial number of reliably documented instances of fatal microshock is consistent with this theoretical estimate that the actual risk is very much less than the risk of being struck by lightning and very close to the risk of being struck by a meteorite.
Consider briefly some of the component factors. Protecting the exposed ends of the indwelling leads is a relatively simple safeguard to implement, that could reduce p5 to a much smaller value than was used in the analysis. Likewise with these special patients, it is particularly important that the use of obsolete, deliberately grounded leads be avoided.

For special equipment, such as cath lab ECG monitors, that might be connected directly to an indwelling conductive lead, (eliminating several substantial layers of protection), it is appropriate to specify a leakage current standard that is as close as possible to an intrinsically safe level. In the U.S., this standard is supposedly based on the published scientific reports and is set at 10 microamperes. The IEC standard is based primarily on published European fibrillation studies and the standard (for cardiac connections) is set at 50 microamps. Since there is a well-documented risk of spontaneous fibrillation, presumably resulting from physical stimulation by catheter, a further mitigating factor (which is not always considered) is that the medical team is prepared to handle this complication. This additional factor of preparedness reduces the actual risk still further.

ILLUSTRATIVE ANALYSIS OF THE RISK OF “STARTLE SHOCK.”

It is theoretically possible for a patient to be injured as the result of a member of the staff, such as a surgeon, being startled by a minor electrical shock while he is performing some kind of critical maneuver on the patient.

For a member of the staff to receive even a minor electrical shock, several factors with their associated probabilities must combine:

- **P1.** Assume that there is a 99% probability that there is at least one piece of line powered equipment within reach. ........................................ 0.99

- **P2.** Assume that there is a 95% probability that the equipment has exposed metal that could become “live”. . 0.95

- **P3.** Assume that there is a 10% probability that the device has 250 microamps of leakage current flowing to the chassis. .......................... 0.1

- **P4.** Assume that the probability that the device becomes accidentally ungrounded is 25% ........................................ 0.25

- **P5.** Assume that the probability that the staff member will touch the ungrounded metal surface is 25% . 0.25

- **P6.** Assume the probability that there is a second grounded metal surface within reach is 80% .......................... 0.8

- **P7.** Assume the probability that the staff member will touch the grounded surface is 25% .......................... 0.25

- **P8.** The threshold of perception for the bulk of the adult population lies in the range 500 — 1000 microamps. A current of 250 microamps can be perceived by only about 10% of the adult population ................. 0.1

The combined probability of a member of the hospital staff being startled by leakage current is, therefore, about $1.12 \times 10^{-4}$.

The probability that the staff member is engaged in a critical maneuver at this time will be low, (1 chance in 5000) $2 \times 10^{-4}$.

This reduces the probability of a patient injury to $2.2 \times 10^{-8}$, and the expected number of injuries (not necessarily fatal) per year from this source to about 0.8.

SUMMARY AND RECOMMENDATIONS

Be prepared to analyze each area of theoretical electrical hazard before deciding to install expensive safeguards such as GFCI's or isolated power systems. Document the reasons for any decisions.

In many instances the existing safeguards provide sufficient layers of protection to reduce the risk to very small levels. Because of previous overemphasis of the problem, electrical safety precautions usually take up a larger share of the hospitals biomedical equipment safety budget than is justified by the actual hazard level. Hazards arising from the use or misuse of equipment in the hospital typically outnumber electrical safety hazards by 10 or even 100 to 1.