Guidelines for Clinical Engineering Programs

Part I: Guidelines for Electrical Isolation
Part II: Performance Evaluation of Clinical Engineering Programs

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In a four-part series, the Journal of Clinical Engineering will present significant guidelines developed at the Shared Biomedical Engineering Service of the Council Shared Services, a subsidiary of the Hospital Council of Southern California. Because these guidelines will be of interest to our readers nationwide, they will be presented in this and the following issues of this Journal....A. F. Pacela, Publisher

ABSTRACT: This 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. In Part I, specific recommendations are given for the use of insulated approach, battery-powered monitors in surgery, and for isolation requirements for devices connected to cardiac leads. In Part II, checklists are provided for the self-evaluation of an in-house, biomedical engineering staff. Parts III and IV, in future issues of this Journal, will include discussion of the theoretical electrical hazard potential in reference to the use of isolated power systems. The question of whether isolated power should be required in all anesthetizing locations will be discussed in Part IV.

Key Words: Electrical Safety; Isolated Power; In-House Service Programs; Electric Shock; Guidelines, Clinical Engineering Programs; Isolated Inputs.

PART I: ELECTRICALLY ISOLATED INPUTS AND OUTPUTS

WHAT KIND OF PROTECTION DO ISOLATED PATIENT CONNECTIONS PROVIDE?

With the increased use of electrically powered monitoring and treatment equipment in hospitals, patients (and staff) are becoming much more vulnerable to electrical injuries, such as burns and electric shock, which can occur when electrical currents pass through a part of the body where they were not intended to pass.

The very best way of protecting patients (and staff) from unintended electrical currents is to insulate them completely from all contact with conductive surfaces, including grounded metal. An acceptable alternate approach to electrical safety, which has been widely adopted in this country, is to connect all exposed metal in the vicinity of the patient to either the utility grounding system or to a local grounding point. In practice, neither approach is sufficient in itself and both techniques are usually employed.

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One obvious drawback is that neither approach is immediately applicable if monitoring system electrodes must be connected to the patient or if the patient has to be treated with a current-delivering device such as a defibrillator or an electrosurgical unit. In both of these cases, isolating the patient connections (the input circuit or output circuit electrodes) from ground or any other circuit which may simultaneously be in contact with the patient's (or staff member's) body provides an important additional layer of protection, particularly if the common grounding (or so-called equipotential) philosophy is being employed. In one sense, the electrical isolation of electrodes connected to the patient is an extension of the "insulate-the-patient" philosophy.

While the end result is the same, the nature of the protection provided by isolated input circuits is different from that provided by isolated output circuits and both cases will be discussed separately.

**ISOLATED INPUT CIRCUIT CONNECTIONS**

The intent in isolating the input circuits of monitoring devices such as ECG monitors is to block the passage of ground-seeking currents which may be introduced to the body through accidental (or deliberate) contact with other conductive electrodes or surfaces.

As far as we can determine there are no specific requirements for electrically isolated input circuits in any of the present codes governing hospital equipment. There are requirements in some standards for devices which are especially designed for connection to cardiac leads and catheters. The 50 microamp standard for 60 hertz leakage current from patient connections to ground in California's Title 22 (and other standards) has been cited by others as evidence that ECG monitors using a grounded right leg lead are "illegal," but we cannot agree completely with that particular interpretation. A monitor using a grounded right leg lead which also has more than 50 microamps of ground lead leakage current would be out of compliance with the Title 22 requirements. This technicality apart, however, we do recommend that hospitals consider this particular type of monitor technically obsolete and plan to replace it as soon as it is economically feasible. In the interim, it would be prudent to avoid using monitors with grounded electrodes on patients who may be connected to multiple sensors or to energy-delivering devices such as defibrillators or electrosurgical units.

A test for 60 hertz isolation from ground is described in UL544 Standard for Medical and Dental Equipment, in proposed standard NFPA 76B, and in the AAMI electrical safety standard. This test has been given fairly wide publicity by manufacturers of electrical safety testing devices. It also was included as Test 5 in the California Hospital Association (CHA) Electrical Safety Manual, which was published in 1972. Some confusion arose over this test because it was frequently described as a way of measuring electrical leakage current. The test, however, does not measure "leakage current" in the conventional sense; it really measures 60 hertz isolation-from-ground. In the test, a 120 volt 60 Hz source is applied to the patient connection through a current limiting resistor and the current which flows to ground is measured. The criterion for adequacy specified for the test is 10 microamps at the terminals on the apparatus (equivalent to an impedance of 12 megohms), or 20 microamps at the patient end of a patient cable connected to the apparatus. However, as stated earlier, we know of no similar isolation requirement in any of the codes or accreditation standards governing hospitals, and we do not think that it is a particularly good idea to use this test or this particular specification of input isolation for any general purpose monitoring systems or devices. For monitoring systems and any other passive device which is intended for connection to an intracardiac lead or conductor we recommend that you specify that the system or device be suitable for such use and that it be so labelled. In this particular case, the isolation impedance criterion discussed above is the appropriate standard to use. This test is described under "sink tests" for use on electromedical apparatus with isolated patient connections in the AAMI Standard on Safe Current Limits and in a section of the NFPA 76B Standard for the Safe Use of Electricity in Patient Care Areas of Hospitals.

One aspect of input circuitry isolation which has received inadequate attention is the impedance-to-ground in the frequency range commonly used for electrosurgery (0.5-2 MHz). An isolated-input ECG monitor with 12 megohm isolation at 60 Hz may have an impedance of only several hundred ohms at electrosurgical frequencies. If a monitor is to be used with an electrosurgical unit, the possibility of current escaping to ground or short circuiting to the indifferent electrode, through the input connections of the monitor, should not be ignored. This is particularly important if needle electrodes are being used. Serious burns can result if the density of the stray radio-frequency current becomes high at the electrode sites. Because the current level at which an injury would occur will vary with the nature and size of the contact area, we cannot recommend a particular RF impedance or isolation level to specify. In those circumstances battery-powered monitors, especially those with isolated input circuits, should be given special consideration because they can provide higher levels of high frequency isolation if the chassis is *not grounded* by a line cord, auxiliary grounding wire, or contact with a conductive floor. We also recommend
that you give preference to units which have chokes in series with the input connections since these will increase the high-frequency isolation.

**ISOLATED OUTPUT CONNECTIONS**

Most modern devices which are designed to deliver current to the body use an isolated output circuit configuration. This helps to confine the delivered current to the intended path through the body. Hazards may arise when these therapeutic currents escape from the intended path and exit the body via other conductive contacts. For example; if a defibrillator could be made so that both paddles were perfectly isolated from ground, the discharge current would pass only when there is a suitable conductive path between the paddles. If only one paddle were applied to the patient and the unit fired, no current would flow. On the other hand, if one paddle were grounded and there were parallel paths to ground through other conductive surfaces connected to the patient’s body, some fraction of the delivered current would pass from the active paddle directly to ground through the parallel grounding paths. The current levels in the intended and the unintended paths will be in inverse proportion to the relative impedances of those paths. In the past, when grounded paddle defibrillators were still available and grounded electrode monitors were in use, defibrillator burns at electrode sites were not uncommon. Grounded paddle defibrillators are no longer available on the general market; any remaining units should be removed from service.

In the case of electrosurgical units, some controversy continues about the relative merits of isolated output versus non-isolated output devices. If the patient’s body is not connected directly, or indirectly, to ground, the output current can flow through the body only between two connections which are deliberately made a part of the same circuit. In this ideal case, there is no tendency for the current to escape to ground and both isolated and non-isolated output devices are equally acceptable. However, in the real world, surgical patients cannot be totally insulated from ground and ESU’s cannot be fabricated with totally isolated output circuitry. Use of an isolated output unit reduces the probability of accidental burns or shock in the following situations:

1. Normal operation in the presence of many spurious patient-ground contacts, e.g. to a grounded table or leg stirrups.
2. A break in the return path from the indifferent electrode.
3. Poor contact between the patient and the indifferent electrode.
4. A faulty device which applies a considerable level of 60 Hz leakage current to the patient.

But the isolated output unit will create a greater hazard than a non-isolated output unit in the following two situations:

5. The surgeon or an assistant, delegated to operate a footswitch, activates the active electrode prior to touching the electrode to the patient. While no injury at all can arise from the non-isolated output device in this situation, the potential leakage from the indifferent electrode of the isolated output unit will depend upon the degree of isolation achieved and, in a well-designed unit, the hazard will be small.

6. The surgeon sparks the active electrode to ground either accidentally, or deliberately, to test the ESU.

Analysis of the relative merits of isolated vs. non-isolated output ESU’s from a safety viewpoint then becomes a question of weighing the relative probability and relative potential for injury, in each of the six situations described.

While situation (5) is probably the most common, the actual hazard level from a well-designed isolated output unit will be very small and probably outweighed significantly by the advantages of the isolated output unit in situations (1) through (4). Situation (6) is primarily a user-education problem, and probably the least common problem. Until recently there was a general consensus in favor of electrosurgical units with well-designed isolated output circuitry. However, there are now at least two electrosurgical units on the market with ground-referenced output circuits (i.e., low impedance to ground at radio-frequencies, but high impedance to ground at 60 hertz), which claim that they avoid the disadvantages of grounded output circuitry by incorporating special monitoring and alarm circuits. For further discussion of the relative merits of these units, see *Health Devices*, Volume 6, pages 59-86 and pages 119-121.

In California, Title 19, the *State Fire and Panic Regulations* reference NFPA Standard 56A (Inhalation Anesthetics). Section 3417 of this standard (which became Section 3777 of the 1973 edition) requires that “Equipment which introduces current to the patient’s body shall have the output current isolated from ground to mitigate against an unintentional return circuit through the patient.” We recommend that this requirement be written into the hospital’s general condition of purchase document and be used for the purchase of all new defibrillators, electrosurgical units, external pacemakers, electroshock units and any other energy-delivering devices.

**SUMMARY OF RECOMMENDATIONS**

1. As far as possible, use the “insulated” approach to electrical safety. Insulate or cover as many as possible of the metal surfaces with which patients or staff may come into contact. This becomes more im-
important as the patient’s exposure to multiple electrically-powered devices increases and as the likelihood of being subjected to energy-delivery devices such as defibrillators and ESU’s increases.

2. Ungrounded, battery-powered monitors are to be preferred in surgery. Install series RF chokes in the input leads of all monitors attached to patients undergoing electrosurgical procedures.

3. Special isolation requirements (6-12 Mohms at 60Hz) should be specified for devices which may be connected to cardiac leads or conductors.

4. Relegate monitors with grounded right leg leads to areas of the hospital where they are likely to be used least.

5. Remove any defibrillators, with a grounded paddle configuration, from service.

PART II: MEASURING THE PERFORMANCE OF THE HOSPITAL’S CLINICAL OR BIOMEDICAL ENGINEERING PROGRAM

Until recently, the clinical or biomedical engineering program in most hospitals was so straightforward that the term “program” was inappropriate. It consisted simply of some provision for getting the hospital’s patient care equipment repaired when it needed it. This was usually handled by the individual department heads negotiating service contracts with either the equipment manufacturers or a small independent service company. The typical annual budget, if you added all of these service costs together, amounted to about 0.5% of the hospital’s expense budget.

With the new equipment and environmental safety requirements imposed on the hospital by the State Department of Health and the JCAH, this budget has increased by approximately 50 percent. In addition, increasing pressures from insurance underwriters, the embryonic Health System Agencies, and various other groups for hospitals to add further technological capabilities to their biomedical engineering programs could drive expenditures up in this area even further.

As the program is expanded to meet these new requirements, and its budget grows, it becomes more important to make sure it is managed properly. A question that we hear more and more from our member hospitals is: “Am I using the best combination of service contracts and other biomedical service resources in my program?” To answer that question, the hospital must be able to measure the performance of its current program and analyze how taking up other options would improve or detract from that performance.

This report outlines methodology and techniques for measuring the performance of a typical biomedical engineering program. The techniques can be used to analyze large programs with in-house biomedical staff and small programs that rely almost exclusively on outside service vendors. (Other options, such as adding full time engineers or technicians to the hospital staff were analyzed in other HCSC reports.)

PERFORMANCE CRITERIA

Without expert help, measuring the performance of a biomedical program is not easy, and very few hospitals have made a serious attempt to do so. Evaluations such as those paraphrased below reflect the problem.

“The program is fine, it got us through our survey without any serious citations.”

“Our program is OK. We get very few gripes from the staff.”

“It seems to cost a lot, but we have the finest program in the area.”

“We run a pretty tight ship in the biomedical area. Nobody gets a better deal from the service vendors than we do.”

A proper assessment of the program requires evaluation of not only the cost, nor the user satisfaction, but a combination of factors.

- **Scope**: Does the program provide all of the necessary or desired services?
- **Effectiveness**: How well does the program accomplish its (defined or undefined) goals?
- **Efficiency**: How much does the program cost, relative to other ways of meeting the same goals?

SCOPE: THE “FULL-SERVICE” PROGRAM

The overall mission of the biomedical engineering program should be to provide the expert support needed to ensure that:

(a) the equipment available meets the hospital’s needs;

(b) the equipment is safe at all times and operational for as much of the time as possible; and,

(c) the staff has confidence in the equipment and is familiar with how to use it properly and safely.

This expansion in scope from a simple concern about maintenance is a direct consequence of the increasing cost and complexity of modern medical equipment.

HANDS-ON SERVICES still account for the lion’s share of the budget. This includes making the necessary repairs to the equipment; making periodic calibration or performance checks on critical devices;