A PREVENTIVE MAINTENANCE AND ELECTRICAL SAFETY INSPECTION SYSTEM FOR A RURAL COMMUNITY SMALL HOSPITAL

by

STEPHEN CHARLES RICHARDS

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Major Professor

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I. INTRODUCTION: The Need

In 1975, electronic and electromedical patient care equipment in use in the United States will exceed ten billion dollars in value. The 1975 annual market, alone, for such equipment will be another one billion (1). With X-ray and laboratory generally being the only "money-making" departments of the hospital, spiraling costs pressure the hospital administrator to constantly seek greater economic efficiency. At the same time, competition and community responsibility behoove the hospital to invest in more of the increasingly sophisticated technical marvels as they are added to the medical practitioner's bag of tools. Part of the problem is, then: How to achieve maximum service for the medical equipment dollar.

With the advent of the new consumerism has come the realization that the medical patient is very much in the consumer role. Almost any product or service has the potential to do harm when it is abused. This is especially true of Medicine. Accordingly, the patient's right to accountability in those responsible for medical care delivery has been strongly reaffirmed.

The nature and condition of medical hardware affects the practitioner's ability to meet this responsibility in at least two ways. First, he must be able to rely on a piece of equipment to perform as expected; to cause the desired diagnostic or therapeutic effect. Secondly, medicine, virtually by definition, involves procedures that tread the thin line between benefit and hazard. For faulty equipment to inject hazards of its own making might become construed as negligence, because many of these faults can be prevented or readily corrected.

We are then concerned with the pursuit of three virtues; economy, reliability, and safety. These problems overlap in cause and effect, and

share a common solution; Medical Equipment Control. An equipment control program implies at least three facets: careful selection of new equipment, education of equipment users, and prompt, regular maintenance. The last of these, Preventive Maintenance (PM) may offer the greatest return on the investment of time and money. PM has been standard practice in many sections of profit-oriented industries for several decades. However, because the benefits in the hospital aren't well understood, and because initiating a PM schedule is a lengthy task, it is frequently left undone.

In the following, we propose an approach to preventive maintenance, with special concern for the problems of the small (less than 150 bed) hospital usually associated with a rural community. The system described was designed for Memorial Hospital, a 65 bed facility in Manhattan, Kansas. However, the procedures and philosophies discussed should, in large part, apply to most small and many larger hospitals.

II. PREVENTIVE MAINTENANCE: Philosophy and Practice

2.1 Definition

Preventive maintenance (PM) may be defined as regular, scheduled inspection and care of electrical, electronic, electromechanical and mechanical equipment. The keys to successfully applying this definition are "regular" and "scheduled." The obvious, but often overlooked goal of PM is to correct conditions leading to equipment failure significantly prior to major degradation. The only way this can be met is by ploddingly persistent regularity of attention. Considering the demands of general maintenance a rather rigorous PM schedule is necessary (2,3,4).

There are a number of strong arguments that plant maintenance (primarily mechanical equipment) and medical equipment (mostly electromechanical and electronics) should be separate spheres of responsibility. However, in this discussion, they shall be treated jointly for several reasons. Primarily, few small hospitals can afford to support an engineering-technical staff separate from their plant maintenance department. Even if they can, certain responsibilities will always overlap, e.g., electrical safety with respect to the power distribution grounding system. Also, the concern here is with procedures, records, and scheduling. Comments on work distribution will be made, but local judgement is best applied at this point. In any case, recording and scheduling can just as well be done for both categories simultaneously.

In following the above definition, PM personnel will attend to seven basic considerations for each piece of equipment, where applicable.

1. Is the equipment operating properly? Does it perform its intended functions with satisfactory accuracy and reliability?

2. Is the equipment safe or does it represent an undue hazard to patients or operators?
3. Is the device in good mechanical and electrical condition? Check for loose, damaged, or missing parts, safety shields, mechanical or electrical connections, and strain reliefs.
4. Is there a complete stock of accessories, expendable supplies, and spare parts appropriate to the location?
5. Carry out recommended PM procedures. Special attention should be given to calibrations, adjustments, lubrication, and procedures recommended by the manufacturer as periodic maintenance.
6. Clean the device and accessories. Cleanliness aids in sanitation, improves confidence in the equipment, and makes it easier to observe for proper operation between PM periods. Dirt can also promote degradation of many types of equipment.
7. Record work done for PM records. If corrective maintenance beyond the scope of PM is needed, order it. If the equipment is unsafe, make the appropriate notifications and have it removed from service. For all equipment, but especially critical patient-care devices, make every effort to minimize its time out of service.

2.2 Motivation and Philosophy

One may properly question why such a thorough effort is necessary. The best motivation comes from the hospital's foremost responsibility, the patient's welfare. Toward this, PM will increase equipment reliability on several counts.

First, it is very disconcerting for a nurse to go through an entire stock of a given device, only to find that none of them function properly in a critical situation. Even a device that appears to function well may give

results far from those desired. Surveys have shown many X-ray generators giving excessive doses and many defibrillators delivering energy far below expected levels. Both cases are examples of faulty calibration. The possible severity of such unwitting errors should be obvious.

With preventive maintenance, the frequency and duration of downtime of important equipment should be greatly reduced. Further, with PM scheduling, such downtime can be scheduled to cause minimum disruption, instead of coming at the least opportune moment. Aside from inconvenience and hazard to the patient, every hour that medical personnel spend coaxing balky equipment is expensive maintenance. In addition to the delay and expense of equipment failures, if the device is a charge item, downtime means lost revenue to the hospital.

Proper PM will also reduce the number and severity of accidents and incidents involving equipment failure. When incidents do occur, PM records should prove helpful in investigation of the cause.

Should litigation result from equipment problems, PM will place the hospital on more solid legal ground. The likelihood of equipment failure will have been reduced. PM records can demonstrate that the hospital has made a reasonable effort to that end, and therefore, should not be found at fault. Without regular maintenance, equipment failures and accidents can be construed as negligence. There are many cases of awards and suits against practitioners and hospitals for the use of unsafe equipment, failure to correct defects, and failure to inspect devices prior to use. The National Electrical Code (NEC), Standards of the Joint Commission on Accreditation of Hospitals (JCAH), and the Occupational Safety and Health Act have placed further responsibility on the hospital. PM is a good, commonsense approach

to this problem. The records that document a good PM program are strong evidence with which a hospital can exonerate itself from claims (3,4,5).

PM records can also be designed to gather data on equipment performance, true operating costs, and other points of interest that should be considered in planning future purchases.

In short, the application of PM does not mean equipment will not fail and hazards will not be present. PM does mean that the frequency of such occurences can be significantly reduced and held to a more tolerable level. PM is the "insurance premium" against much more costly problems. The lack of PM is precisely analogous to buying a car with the intent of never checking its oil or lubricating it "until the need is obvious."

Preventive maintenance begins even before a new piece of equipment is put into service, especially when PM is part of a comprehensive equipment control program. Under equipment control, specifications are drawn and made available to prospective vendors, following a set routine. These should clearly spell out minimum performance standards and general conditions that must be met before a piece of equipment will be accepted and paid for. When a device is selected for purchase and arrives for approval, it should be thoroughly examined against the stated criteria as well as normal PM-type inspections. This should be repeated several times throughout the specified trial period and before final acceptance. At this point, the new piece will be in the flow of the PM schedule.

The economic advantage of PM is perhaps most obvious in extending the life of new equipment. Moreover, surveys have shown as much as 40 to 50 percent of new medical equipment bears some defect when delivered (4). A hospital cannot economically or legally afford not to protect itself from this.

There is some argument as to the benefits of PM for older equipment. However, virtually any piece of equipment in service deserves preventive maintenance. PM will retard degradation, extending the life and reliability of a device, regardless of its age when PM is initiated. This should certainly be the rule for patient care equipment. If the device doesn't fit this rule, a patient should not be subjected to it.

A less rigorous attitude may be applied to plant equipment not directly related to patient care. Still, if a device cannot benefit from PM, one must seriously question the economics of keeping it in service at all.

A new factor must be recognized in the judgement to apply PM. It is the finitude of supplies of energy and raw materials, and the limits this places on the national economy. Energy will become increasingly expensive. Materials and manufactured goods may become significantly more expensive. Delivery times may become lengthy and unpredictable. For the hospital, this means energy must be used as efficiently as possible. Also, many equipment replacement decisions have been based on replacement costs versus maintenance costs. This balance may shift significantly, or replacements may simply become unavailable.

In certain instances, PM will cause equipment to use less energy. If equipment availability and replaceability becomes serious, PM will not only be economically sound, it can be a matter of institutional survival.

2.3 Practice

Accepting the benefits of preventive maintenance, a note of restraint must be added. PM can be overused as can any good thing. Careful records can help show when returns don't match the effort, but recordkeeping is not the primary goal. Certain PM checks can, themselves, degrade the equipment. Therefore, PM intervals should be just short enough to reasonably assure

proper performance. At best, 100% reliability and safety can be approached only by expending enough time and money. How much is a hospital (and the patient) willing to pay for a given degree of security? Judgement and experience must point to the optimal amount of PM.

The following criterion is suggested: adjust PM intervals to find defects in about 5% of inspections (1% in critical areas such as ICU/CCU, surgery, and emergency rooms). This level is generally easy to maintain with few personnel. Before a truly life-threatening situation can occur there usually must be a peculiar combination of circumstances. Therefore, this approach tends to provide much better than 95% (or 99%) reliability for a nominal cost. Additional safety and reliability will tend to be very costly and of questionnable value (5,6).

Finally, a program's effectiveness depends on the distinction between what PM is and is not. PM is not repair and overhaul. In a larger hospital, corrective maintenance assignments destroy the effectiveness of a PM employee by disrupting time and scheduling. This person's attention should be on minor adjustments, cleaning, and inspection as outlined above. If a larger problem is found, steps should be taken to protect the device and those exposed to it, and then order the required work.

In labor assignment, judgement again, is a very important tool in PM, especially in the small hospital. With fewer units to maintain and a smaller staff, there must be a balance between corrective and preventive maintenance assignments. An approach is to note that while the total PM staff may be less than one full-time-equivalent, it will probably be several persons, e.g., one for mechanical plant equipment, one for electronics, etc. The same person may do both corrective and preventive work on a given class of devices, but

the two functions should still be separated enough to assure completion of PM schedules. This might mean devoting alternate days to corrective and preventive assignments, or a similar division of time to the same effect.

Whatever approach is taken to PM, the central issue is to give regular attention to each device.

III. ELECTRICAL SAFETY: A Practical Approach

3.1 Hazards

Since the late 1960's, news media have dramatically reported the presence of subtle but significant electrical hazards that are peculiar to the hospital environment. As with most scares, these reports gave rise to considerable panic, and a plethora of solutions. Many of these solutions are highly profitable to the supplier and very costly to the patient. This is not to pass off the problem as minor, nor profitting from it as improper. Patient safety is never a minor concern, and without profits, solutions would be unavailable. Rather, electrical safety is to be approached with knowledgeable moderation and a special eye for the cost to benefit ratio.

This topic has been singled out as a separate topic in this report for several reasons. Primarily, electrical safety has and will continue to foster much controversy and confusion. It is intended here to offer part of an effective, yet economical, response to the problem. Electricity is omnipresent in the modern health care facility. Many equipment malfunctions can cause improper or inadequate results. However, electricity is perhaps the single factor that can, in and of itself, cause death. It can inflict its damage, often without leaving any pathological trace. Despite this, electrical safety is not chasing spooks. Most conditions that might lead to an electrical incident can be readily detected and corrected. Therefore, the regular inspection that is part of effective preventive maintenance can be the first line of defense against electrical hazards.

The hazards due to electricity in the hospital are basically of two types: fire and explosion due to arcing or overcurrent heating in the presence of flammable materials, and physiological damage due to the passage of current through the body.

Fire and explosion prevention are generally a problem of equipment design and selection. From the maintenance standpoint, if one may assume that equipment has been correctly designed and selected, then procedures are essentially those used to verify equipotential grounding integrity to be discussed later. The assumption is, of course, not to be followed without verification, but that is beyond the scope of this paper.

The principle effects of current passage through the body are heating and the stimulation of nerves and muscles. At least one beneficial side effect of the sudden interest in electrical hazards is an increased understanding of these effects. A good overview of the present understanding is found in "Electrical Safety in the Hospital - 1974," by Fred J. Weibell (7).

Briefly, recall that electrical shock is more than one phenomenon. The terms macroshock refers to any shock due to points of contact, none of which are within or near the heart and within the chest wall. A shock received when at least one contact is within or on the heart tissue (myocardium) is called a microshock. A necessary condition for microshock is a conductive path from outside the body to the heart, but elsewhere insulated from the body. A patient in this state is said to be <u>electrically susceptible</u>.

At this time, there are only three procedures in common use that render a patient electrically susceptible:

1. Insertion of a pacemaker catheter electrode from an external pacemaker.
2. Use of a fluid-filled catheter to measure blood pressure in the vicinity of the heart, to take samples from or inject substances into the vicinity of the heart.
3. Insertion of an electrode into a cardiac chamber for intracardiac ECG measurements.

This means only a small percentage of patients confined to specific areas such as ICU/CCU will be involved. However, these also tend to be patients least capable of coping with this added stress. Note that in the small hospital, procedures 1 and possibly 2 will be the only ones commonly encountered (7).

With the exception of microshock, the mechanisms of electric shock are now fairly well understood. The following are accepted as typical minimum stimulus currents for certain reactions (7).

1 milliampere (500 microamperes or greater): Threshold of perception; a slight tingling sensation and startle reactions may result.

10 milliamperes (5 to 15 mA): maximum "Let-Go" current; muscle contractions may be strong enough to prevent release of grasp by the victim. Currents in excess of 18 mA can contract chest muscles, stopping breathing as long as the current is applied. Breathing will ordinarily resume when current is removed.

100 milliamperes (50 to 500 mA): Fibrillation threshold; ventricular fibrillation may occur. The human heart does not normally resume sinus rhythm spontaneously, even after power is removed. Indications are that fibrillation, not suffocation cause most electrically induced deaths.

1 to 5 Amperes: Complete contraction of the myocardium. Normal sinus rhythm will frequently resume upon removal of current. Thus, there is a band of current levels that appear to be more hazardous than higher currents.

These are statistically derived values, subject to individual differences. Since the physiological effects depend on current density, thresholds also

vary with type and area of contact and the skin condition. There are also dependences on contact positions with respect to the heart and with respect to the frequency of the applied current. Unfortunately, the common power line frequencies of 50 and 60 Hertz fall within the range of maximum sensitivity of about 10 to 500 Hz.

The source of greatest controversy is the scarcity of data on microshock in human subjects. Most of the data on which present standards are based is from a relatively small number of experiments on canine subjects. A canine heart has been shown to fibrillate in response to currents as low as 20 microamperes. Mean fibrillation currents are on the order of 100 to 500 microamperes for canine studies (7,8). Human microshock data is limited to perhaps as few as 20 cases. In these, there is no record of fibrillation from currents less than 80 μA, and in some cases, up to 1500 μA was required. Open heart surgery has been the source of almost all human data.

Existing and proposed safety standards (less than 10 μA allowed in susceptible-patient areas) are based on the minimum fibrillation current shown in dogs. This may seem unnecessarily strict in light of the available human data. However, at least one canine study (Graystone and Ledsome, 1973) has shown that a current level well below the fibrillation threshold will block all ventricular contraction as long as the current is applied. In light of this, it is probably too early to relax the microshock safety limit until justified by further evidence (7).

The question then rises, what are the potential sources of these hazardous currents? The Association for the Advancement of Medical Instrumentation (AAMI) has coined the term "risk current" to describe them. Risk currents actually appear by two different mechanisms, not always distinctly separable.

Leakage current, strictly speaking, is that current flowing between conductors that are intended to be insulated from each other. Leakage is due to the imperfect nature of insulating materials and capacitance between conductive surfaces within the device in question.

Fault currents are those due to an unintentional resistive connection to exposed portions of the device. The path may be due to a misplaced wire or component, dirt buildup, spilled fluids, or a variety of other causes.

Common usage tends to lump all nontherapeutic and/or undesirable currents available from a device as "leakage currents." This is generally acceptable, but the distinction should be understood in order to expedite corrective measures.

3.2 Remedies and Standards

Equipment designs that minimize unwanted currents are generally based on chassis layouts that reduce stray capacitance, high impedance isolation in patient circuits, and careful grounding of exposed metal parts that are not intended to be energized. Preventive maintenance for electrical safety consists largely of verifying the integrity of these measures where applicable.

The issue now becomes: With what standards should patient care devices and other electrical equipment used in the vicinity of patients comply and what measurements will adequately verify compliance? The confusion over shock thresholds is clearly reflected in the variety of standards advanced by at least three nationally recognized sources: AAMI, the National Fire Protection Association (NFPA), and the Underwriter's Laboratory (UL). UL's standards are unnecessarily strict and therefore expensive and bothersome. NFPA's research methods and assumptions are under fire from a number of respected ranks. In fact, at this writing,

NFPA's proposing document, 76B-T "Tenative Standard for the Safe Use of Electricity in Patient Care Facilities," has been sent back to committee for revision. This report will follow AAMI's Safety Standard for Electro-Medical Apparatus. This choice follows closely the reasoning of Emergency Care Research Institute (ECRI) in their publication, Health Devices (9).

AAMI establishes two classes of equipment. Type A is that equipment acceptable for use on electrically susceptible patients. Type B equipment is acceptable for patients that are not electrically susceptible. For Type A devices, the maximum allowable leakage from the ungrounded chassis to ground is 100 μA. The maximum allowable leakage from one patient electrode to another or from a patient electrode to ground is 10 μA, whether or not the chassis is grounded. For Type B equipment, the maximum allowable leakage is 500 μA from the chassis and 50 μA from patient leads (9).

All of these limits and precautions are predicated on the intent to maintain safe conditions even in the event of a few typical malfunctions. However, the first line of defense, even if malfunctions remain within reasonable bounds or especially if they don't, is grounding. The tactic here is to maintain all exposed metal, that is not to be intentionally energized, at the same potential.

Assume that all chassis and major metal surfaces have a low resistance connection to ground. Now assume that a ground fault occurs. (A ground fault is an accidental connection between an energized conductor and a grounding conductor, causing abnormally high current in the grounding system.) In this case, excessive current will frequently trip an over-current device, calling attention to and temporarily eliminating the hazard. At any rate, if the ground path is low-resistance, the IR drop will be small,

creating minimal potential difference between the energized surface and surrounding conductors. Similarly, in the case of leakage, almost all of the current will take the ground path as opposed to the higher resistance path through a patient or staff person. A high-resistance ground path will conversely cause significant IR drops, increasing the hazard. Therefore, an inspector should be at least as concerned about the quality of grounding as with the condition in the ungrounded mode.

3.3 Procedure

Electrical safety inspection should include the subset of the following procedures appropriate to the device in question.

1. The line plug should be visually examined to be certain that all prongs, contacts and connections are intact and that the plug is in generally good condition.
2. The line cord and strain reliefs at both ends should be examined while flexed and tugged. Fraying, cracking, excessive abrasion, or other damage calls for a replacement. Tension or mechanical shock on the cord must be relieved so as to place no stress on electrical connections.
3. The grounding resistance between the grounding pin of the plug and exposed metal parts of the device should be measured with a precision ohmmeter. Generally, this should be less than 0.1 ohms. Since it is often difficult to obtain good resolution and accuracy at low resistances, this limit may have to be raised to as high as 0.3 ohms to allow for measurement error.
4. Leakage current should be measured from all exposed metal and patient electrodes to ground and between all patient electrodes. These measurements should be made in all probable modes of operation.

Leakage current can be measured at many points on a device and the device can be connected to power in several ways. Therefore, a complete leakage current inspection involves taking several measurements with the device in different circuit configurations. Some published procedures require as many as 45 leakage current measurements, many of which have been shown to be redundant. Despite this, there is one particular failure mode that can occur in modern isolated ECG amplifiers that commonly goes undetected.

Faulty input isolation amplifiers may inject current from one to another, through the patient. Several published procedures require tests similar to Test 3, following, but make measurements only between lead combinations RA-LA, RA-RL and LA-RL. This is sufficient for older amplifiers in which a differential amplifier is connected directly to LA and RA when Lead I is selected. However, more modern ECG equipment may have isolation amplifiers in each of the patient leads. Failures of the amplifiers in the LL or C leads would not be detected by many presently used procedures.

The following procedure is based on material developed in Departments of Biomedical Engineering within the Veteran's Administration. The procedure is performed in four test configurations and requires only 12 current measurements. Yet, this procedure should detect all probable failure modes of ECG monitors and recorders and is generally applicable to most patient care devices (10).

Selecting a meter with which to measure risk currents requires special attention. The safe current limits quoted previously are actually low frequency values. The body's sensitivity to current varies with frequency. AAMI has adopted the frequency dependence for safe current limits shown in Figure 3.1a. Current limits for Type B devices are 5 times the magnitudes

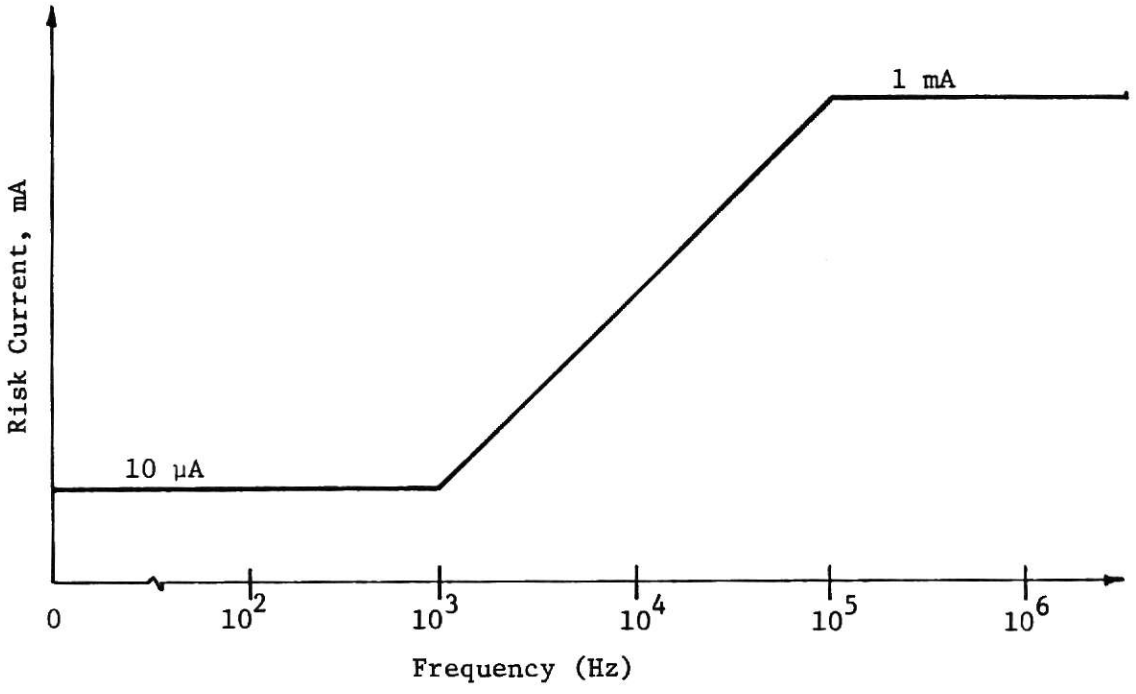

Fig. 3.1a. Maximum Risk Current Limits vs Frequency for Type "A" Equipment.

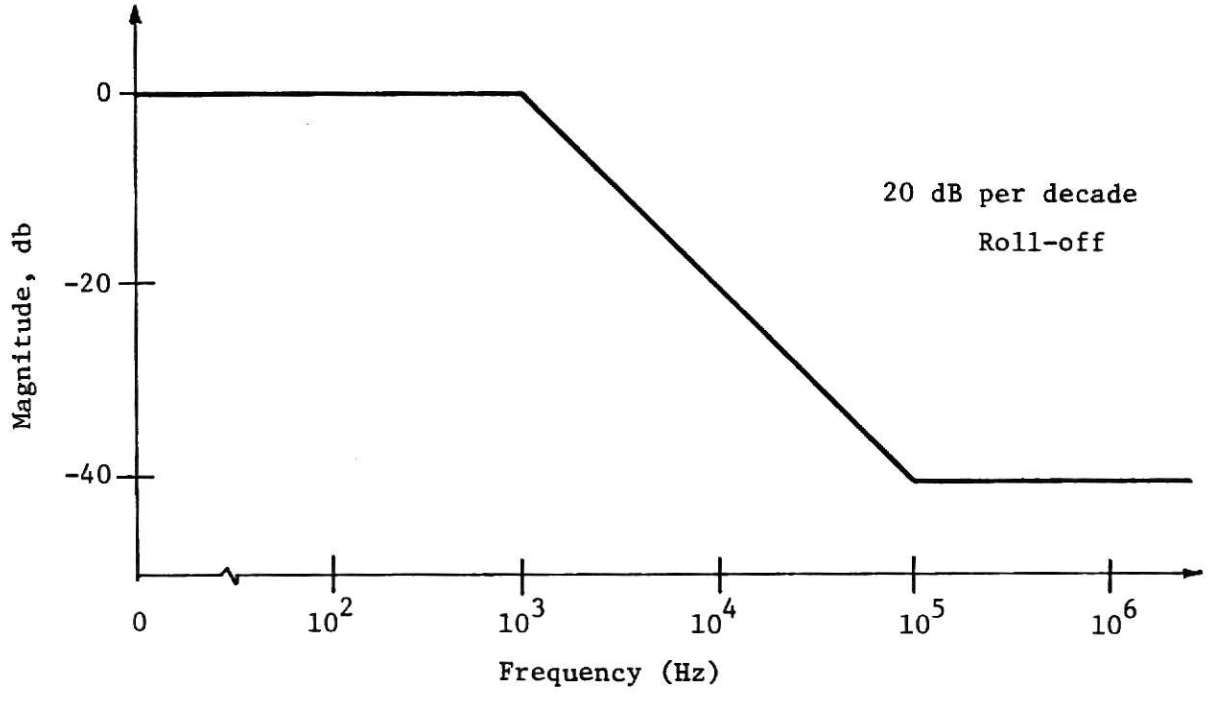

Fig. 3.1b. Magnitude vs Frequency Characteristic of AAMI Test Load.

in Figure 3.1a. It would be bothersome at best to determine the frequency content of risk currents during routine inspections. Instead, a test load can be used for the measurements. Using a load with a transfer characteristic that is reciprocal to Figure 3.1a, the meter may be read as though all leakage is low frequency. The desired characteristic is shown in Figure 3.1b (8).

This characteristic was originally accomplished with networks of the form of Figure 3.2a. At low frequencies, the capacitor appears as an open circuit and the current is imposed on a 1 Kilohm load. By Ohm's Law,

$$V = IR, \quad \text{or} \quad I = V/R, \quad \text{yielding}$$

millivolts/Kilohms = microamperes.

Thus, the millivoltmeter can be interpreted as reading directly in microamperes of risk current.

It has been found that this test load doesn't give accurate results when the source impedance is low and the current contains high frequencies. Assume that the source impedance, Z_s, is large with respect to 1K, and that the millivoltmeter is of high impedance. The risk current, I_r, can then be viewed as a Norton equivalent as in Figure 3.2b, where V_s is the source voltage. Under these conditions, the meter will accurately represent the risk current.

Now, assume the source to be of low impedance. It will then act as a voltage source similar to the Thevenin equivalent in Figure 3.2c. If Z_s is small with respect to 1K ohm, and especially if it is small with respect to 10 ohms, the voltage across the load will not vary significantly with frequency. The desired transfer characteristic is not followed and the meter readings will be erroneously high in the presence of high frequencies (11).

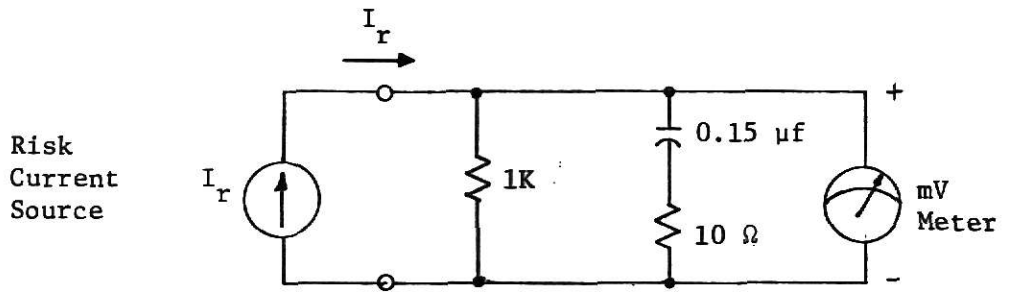

Figure 3.2a. 1974 AAMI Test Load

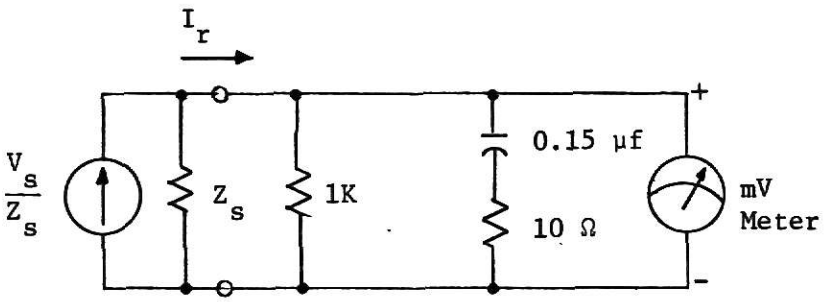

Figure 3.2b. Norton Equivalent Interpretation of Figure 3.2a.

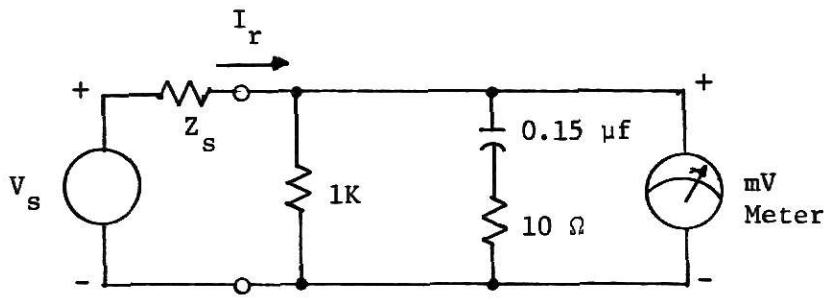

Figure 3.2c. Thevenin Equivalent Interpretation of Figure 3.2a.

In early 1975, AAMI adopted a new test load proposed by the U.S. Food and Drug Administration and the International Electrotechnical Committee. The new load corrects the problem. As shown in Figure 3.3, the high frequency attenuation network is isolated from the source by a 10 to 1 voltage divider. The load that this represents to the source is a constant 1 Kilohm. It will vary with frequency by less than 1%. Therefore, the frequency response of this load will be virtually independent of the source impedance. One kilohm is a typical value of the minimum impedance of the human body (12). Due to the 10 to 1 divider, the meter in Figure 3.3 is calibrated in (mV x 10) μA.

Several meters using the old test load are still available. If a hospital already has one of these instruments, it can be used for most measurements as long as the limitations of its operation are known. If a new meter is to be acquired, it should, in some manner, realize or exceed the new characteristic.

To conduct these tests, the device under test must be connected to a grounded receptacle of correct polarity (NEMA WD1-1971) through an adapter that permits the polarity to be reversed and the ground conductor to be interrupted (Figure 3.4). This adapter can be readily made from common parts.

The test load and meter may also be acquired by modifying existing equipment, as can a power source noted later. However, it may be false economy to build this test equipment in-house, especially if a precision millivoltmeter must be purchased. Several manufacturers offer single-package test systems that include all of the needed functions. These systems are designed to perform the tests in a stepwise fashion that is much simpler and

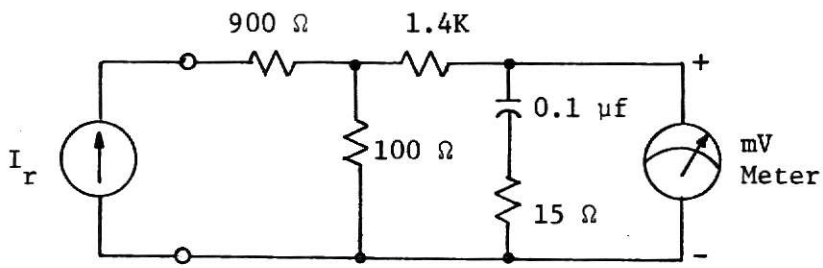

Fig. 3.3. 1975 AAMI Test Load.

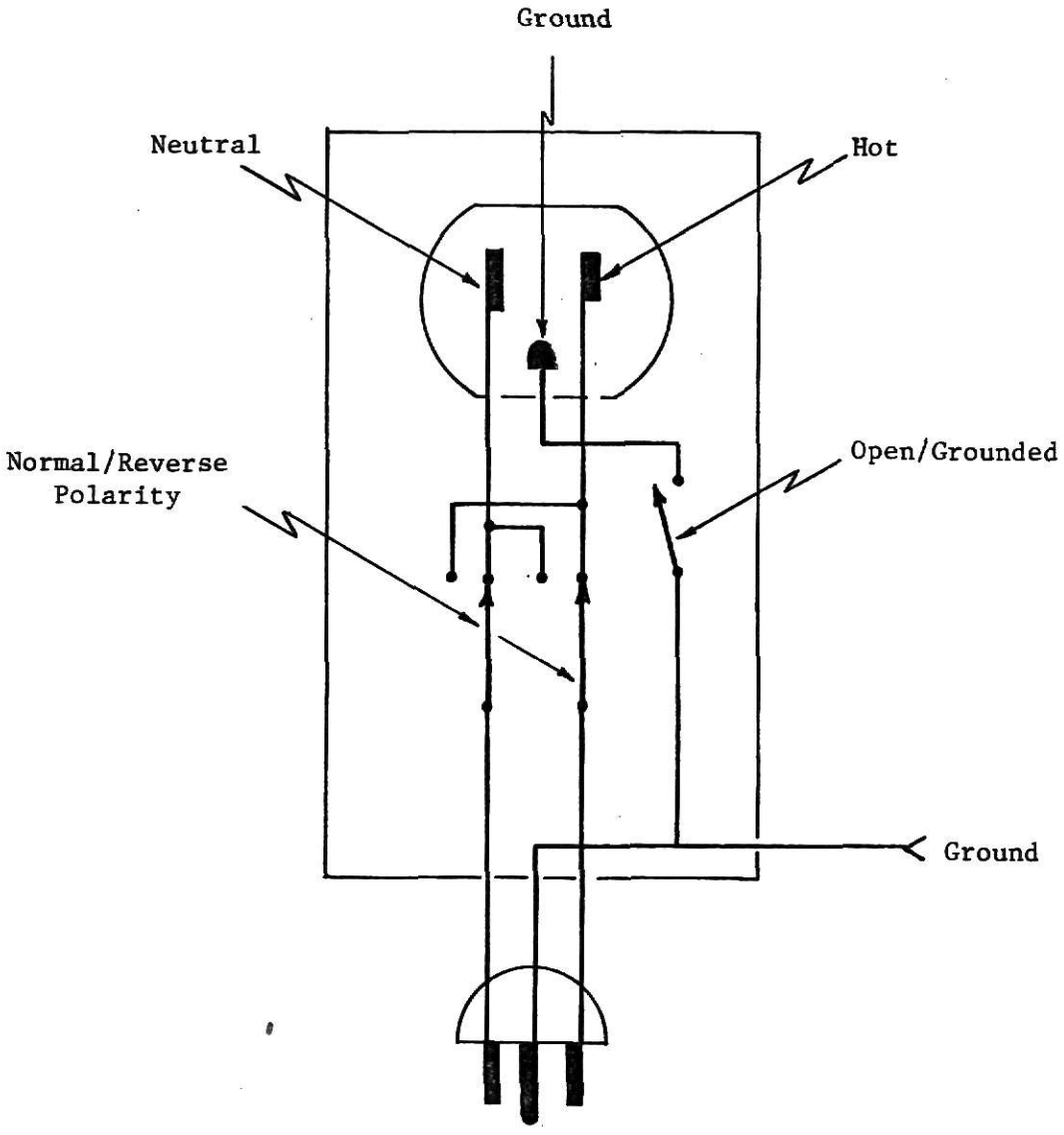

Fig. 3.4. Test Adapter.

faster than with several separate pieces of gear. Besides, the time spent designing and assembling test equipment might be considered time lost on improving the patient environment. Together, the time lost might be more than the price of a good electrical safety analyzer. This is another point at which to apply local judgement to the personnel and facilities at hand.

The procedure is as follows.

Test 1.

The device under test (DUT) is plugged into the test adapter and the leakage current meter is connected between ground and any suitable exposed metal part of the case of the DUT.

Measurement 1.1 (M1.1)

The current is measured under the following conditions:

DUT: off, Ground: open, Polarity: normal. Measurement 1.2

The same as M1.1, except Polarity: reversed.

Interpretation

Referring to Figure 3.5 and the equivalent circuit in Figure 3.6a, the current in M1.1 is due to C_c, the capacitance between the hot wire and ground wire of the line cord. The current of M1.2 includes, in addition, the current through capacitances C_n and C_h. These capacitances are due to the conductive structures within the case that are connected to the neutral and hot wires of the line cord. R is a lumped representation of these structures. Capacitances C_c and C_n place a higher capacitance and thereby a lower impedance between neutral and the case than C_c alone places between hot and the case. In general, the neutral conductor will be connected to or at least floating near ground potential.

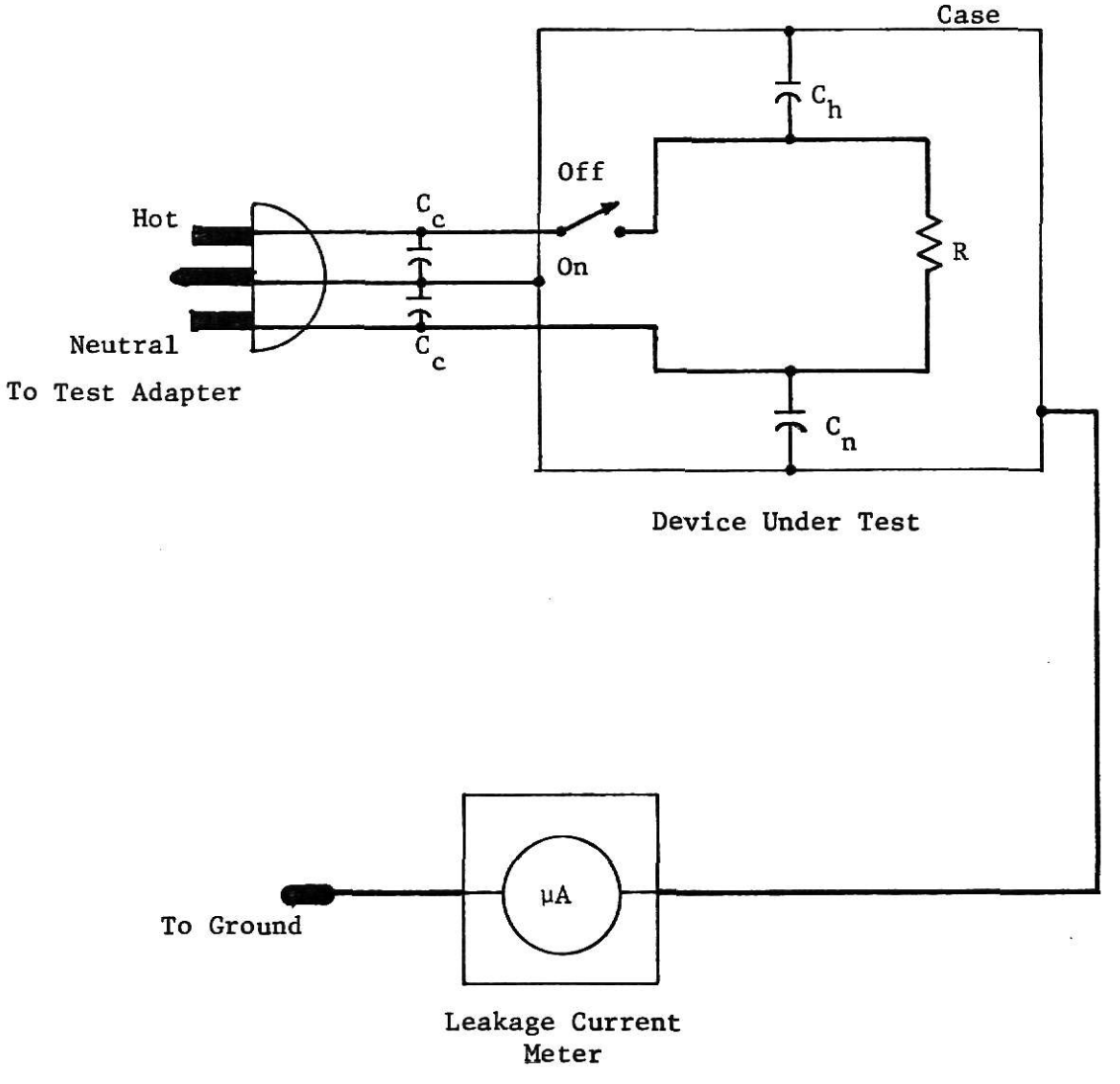
Case
C_h
Off
Hot
C_c
On
R
Neutral
C_c
To Test Adapter
C_n
Device Under Test
μA
To Ground
Leakage Current
Meter

Fig. 3.5. Test 1

In Figure 3.6a, the parallel combination of impedances from the unswitched line to the case will always be less than the cord-capacitor impedance alone from the switched line to the case. Thus, by voltage division, the case potential will be closer to the unswitched line. Placing the switch in the hot line forces the case potential to be closer to neutral, and thereby, to ground potential, when the device is off. Therefore, M1.2 is expected to be greater than M1.1. If the reverse is true, the ON-OFF switch of the DUT may be in the neutral rather than the hot lead. This should be checked and, if verified, corrected before continuing. If the currents are equal, the ON-OFF switch may be a double pole switch or the case capacitances may be small with respect to those of the line cord.

The relative values in M1.1 and M1.2 convey the significant information. The specific values are of little significance.

Measurement 1.3

The leakage current is measured under the following conditions:

DUT: on, Ground: open, Polarity: normal.

Measurement 1.4

The same as M1.3, except Polarity: reversed.

Interpretation

Again in Figure 3.5, the current of M1.3 is mainly due to C_h, the capacitance between the case and structures connected to the hot side of the line. Likewise, in M1.4, C_n between the case and neutral structures is the major factor. In most devices, these two capacitances are unequal. It is considered good practice to wire a device in such a way that the large capacitance is connected to the neutral side in order to minimize leakage under normal operating conditions.

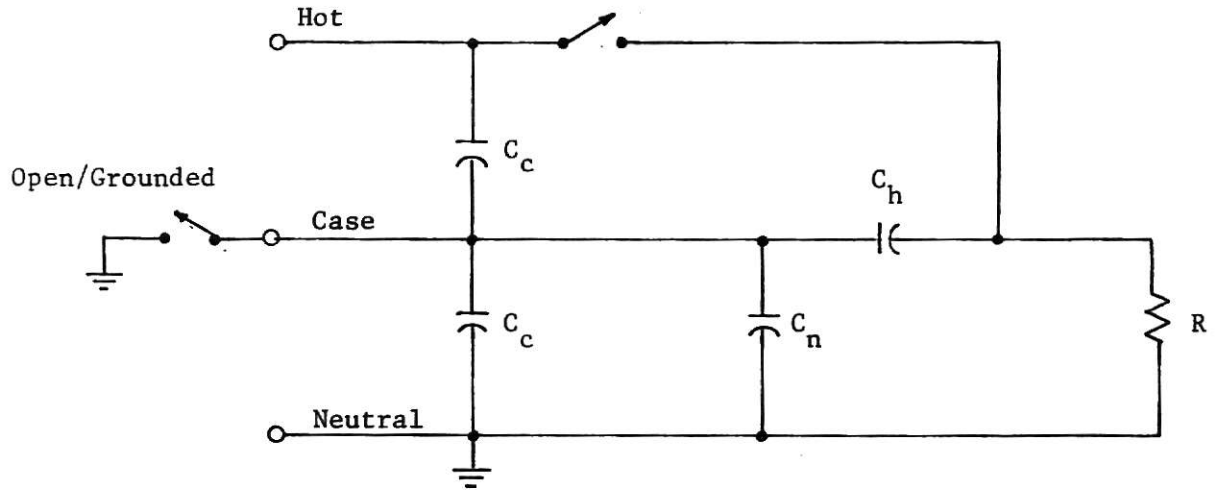

Fig. 3.6a. Measurements 1.1 and 1.2.

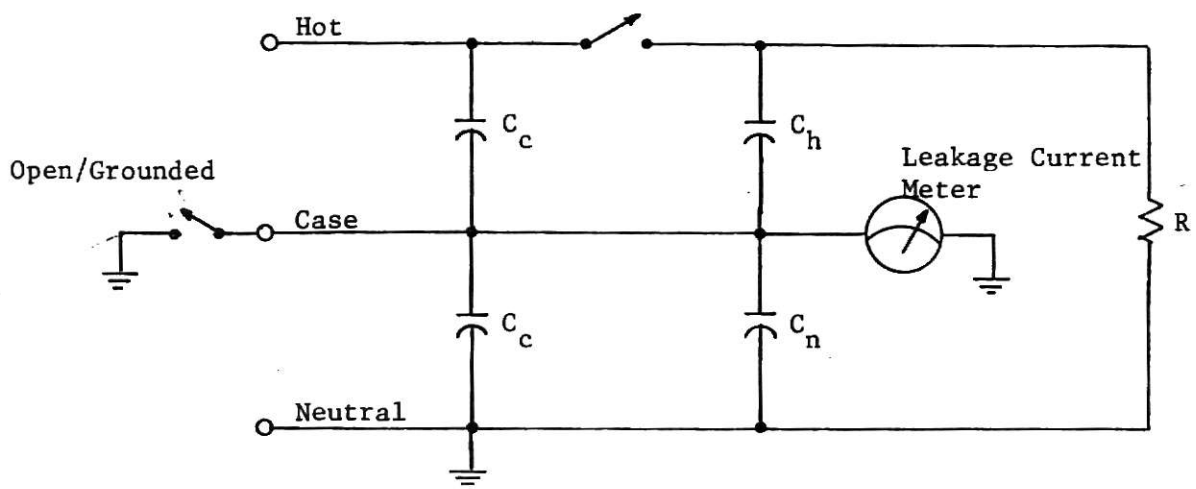

Fig. 3.6b. Measurements 1.3 and 1.4.

Refer to the equivalent circuit in Figure 3.6b. The capactive reactance, X_c is

$$X_c = \frac{1}{\omega C} = \frac{1}{120\pi C} .$$

The potential differences V_h and V_n, between the case and the hot and neutral leads are given by

$$V_h = V_\ell \frac{X_{cn}}{X_{c_h} + X_{c_n}} = V_\ell \frac{C_n}{C_h + C_n}$$

and

$$V_n = V_\ell \frac{X_{cn}}{X_{c_n} + X_{h_c}} = V_\ell \frac{C_h}{C_h + C_n} .$$

V_ℓ is the line voltage.

Again, the neutral is at or near ground potential. If C_n is greater than C_h, then V_n is less than V_h. That is, the case is closer to the ground potential. Thus, the leakage current due to this mechanism is minimized. Therefore, the reading in M1.4 should be larger than in M1.3. If not, the DUT may be wired counter to good practice. This possibility should be checked and changed if it is reasonable to do so. If the readings are equal, the capacitances are coincidentally similar.

The value of current in M1.3 is the only one of significance in this test. It is the chassis leakage current. This is the current that might flow through a person's body under certain conditions. The chassis leakage current shall not exceed 100 μA for Type A devices or 500 μA for Type B equipment.

The chassis leakage current of M1.3 should be recorded. On later PM inspections, this reading should be compared with the previous reading. Small variations can be attributed to changes in temperature and humidity.

Large increases of leakage current may be indicative of the beginning of insulation breakdown and should be investigated. Some manufacturers specify a normal range of leakage current for their devices.

Measurement 1.5

DUT: on, Polarity: normal, Grounded: grounded.

Interpretation

When the case of the DUT is grounded, risk currents should flow through the ground lead and the meter should read zero. A non-zero reading indicates an open or high-resistance ground path. Note that a zero reading is not conclusive. Such a reading can occur when the ground resistance is small with respect to that of the meter. The meter impedance is of the order of 1,000 ohms, so a ground resistance of as much as 10 ohms might still give an indication near zero. This is why a separate grounding resistance check must be made during inspection.

In Test 1, it is assumed that the DUT is equipped with a three pronged line plug (Figure 3.4) and has exposed metal parts. With double insulated equipment, no exposed metal parts are available for connecting to the leakage current meter. For acceptance examination, a metal case may be simulated by forming a piece of metal foil about the exposed (nonconducting) surface of the equipment. This will generally be too cumbersome for PM inspections. If the DUT is double insulated but has a grounding plug with a third pin connected to the unaccessable chassis, the leakage current meter should be connected to the grounding pin for M1.1 through M1.4. Measurement 1.5 cannot be performed on such equipment. If the equipment is double insulated and has no ground pin, none of Test 1 can be done. It is questionnable whether or not such equipment is suitable for Type A applications.

It should be noted that Test 1 is applicable not only to ECG type equipment, but most other medical as well as nonmedical equipment. Tests 2 through 4 pertain more specifically to ECG monitoring devices and equipment with similar patient leads.

Test 2

The DUT is plugged into the test adapter. All patient leads are connected together and are connected to the leakage meter as shown in Figure 3.7. A simple adapter for this consists of six binding posts or alligator clips connected together to hold the patient leads and the meter lead. Several of the commercially available test systems have a bank of built in connectors for this purpose.

Measurement 2.1

Leakage current is measured under the following conditions:

DUT: on, Polarity: normal, Ground: open.

Measurement 2.2

The same as M2.1, except Ground: grounded.

Interpretation

The current in M2.1 is called the patient lead leakage current. This is the current the leads can source through the patient to ground. Comparing this value with the chassis leakage current from M1.3 gives some clue to the configuration of the input stage of the device. If M2.1 is equal to M1.3 most likely one of the leads (RL-lead) is connected directly to the chassis. In this case, Test 4 cannot be performed. Devices of this type shall not be used on patients with intracardiac catheters and the device shall be so labeled.

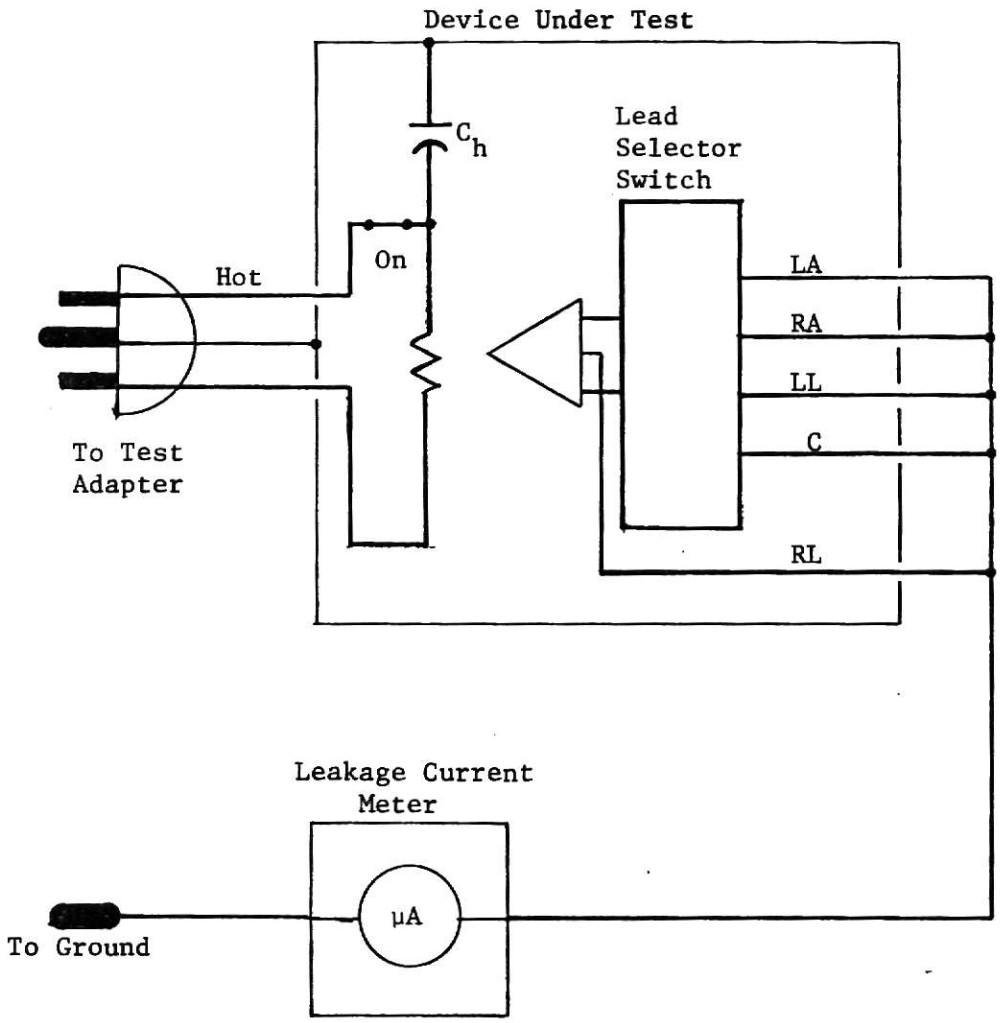
Device Under Test
C_h
Lead
Selector
Switch
On
Hot
LA
RA
LL
C
RL
To Test
Adapter
Leakage Current
Meter
μA
To Ground

Fig. 3.7. Test 2.

If the leakage current measured in 2.1 is smaller than the chassis leakage current of 1.3, the DUT may be equipped with isolated patient leads. Test 4 is to verify this possibility.

Because the current of M2.1 could, under certain circumstances, pass through the patient's body, it is to be limited. Its magnitude should not exceed 10 μA.

In M2.2, the reading should be zero if the RL-lead is case-grounded, because any leakage should flow through the ground lead. This measurement is redundant but should be performed to verify M1.5 because of the importance of an intact ground lead. If the device has isolated inputs, M2.2 may be non-zero, but should be less than 10 μA.

Test 3

The RL-lead of the patient cable is connected to one terminal of the leakage current meter as in Figure 3.8. This terminal may be grounded. For this test, the meter must respond to direct current. This should be verified from the meter specifications.

Measurements 3.1 through 3.4

The leakage is measured under the following conditions:

DUT: on, Polarity: normal, Ground: grounded,

Device lead-selector switch (if provided): Lead I

The leakage current is measured between the RL-lead and each of the other two (or four) patient leads (depending on whether the device has a three- or five-lead patient cable.

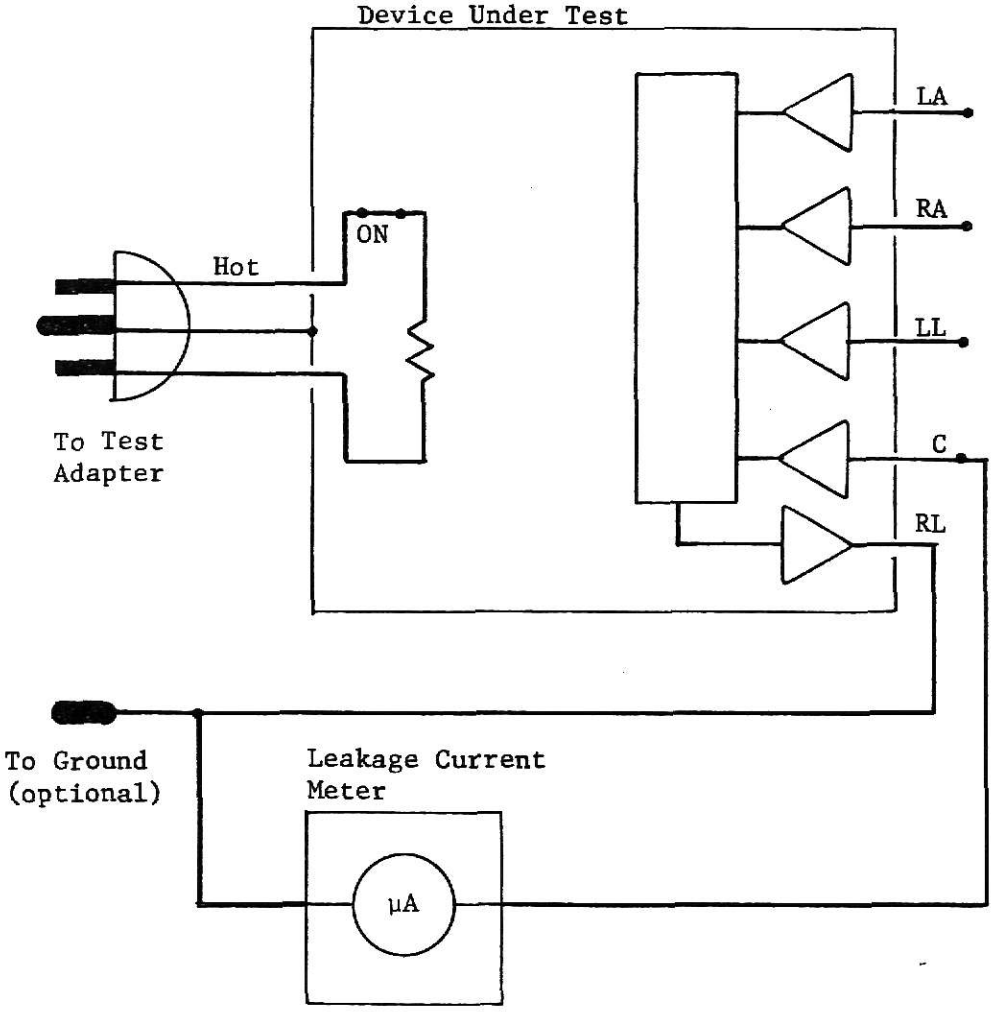
Device Under Test
LA
RA
LL
C
RL
ON
Hot
To Test
Adapter
To Ground
(optional)
Leakage Current
Meter
μA

Fig. 3.8. Test 3.

Interpretation

The purpose of Test 3 is to detect currents that may be injected into the patient leads by faulty input stages of the amplifiers. The only current that should normally flow in any of the patient leads is the bias current of the first transistor, which should be less than 10 μA. Any current over this may indicate a malfunction and further tests should be run to find the source.

Test 4

The purpose of Test 4 is to verify the presence and condition of isolated patient inputs. Such inputs provide a very high input impedance necessary for Type A applications. If a hazardous voltage is applied to the patient by another source, a monitor may provide a sink to ground for the risk current. If the monitor input impedance is not sufficiently high (greater than 6 Megohms) the sink current may be excessive (>20 μA).

A source of 115 VAC is required for this test. If the leakage current meter can be operated in a floating configuration, the circuit in Figure 3.9a can be used (Battery-powered meters usually allow this and commercial systems may have this mode built in.) If one terminal of the meter is grounded, an isolation transformer must be used as in Figure 3.9b. A method of improvising and isolation transformer from two identical, inexpensive filament transformers is shown in Figure 3.9c. The 470K ohm resistor in all three circuits limits the current to protect both the operator and the device under test. Test 4 again requires all patient leads to be connected together. The adapter from Test 2 can be used.

Measurement 4

With externally applied voltage as shown in Figure 3.9, measure the current into the patient leads under the following conditions:

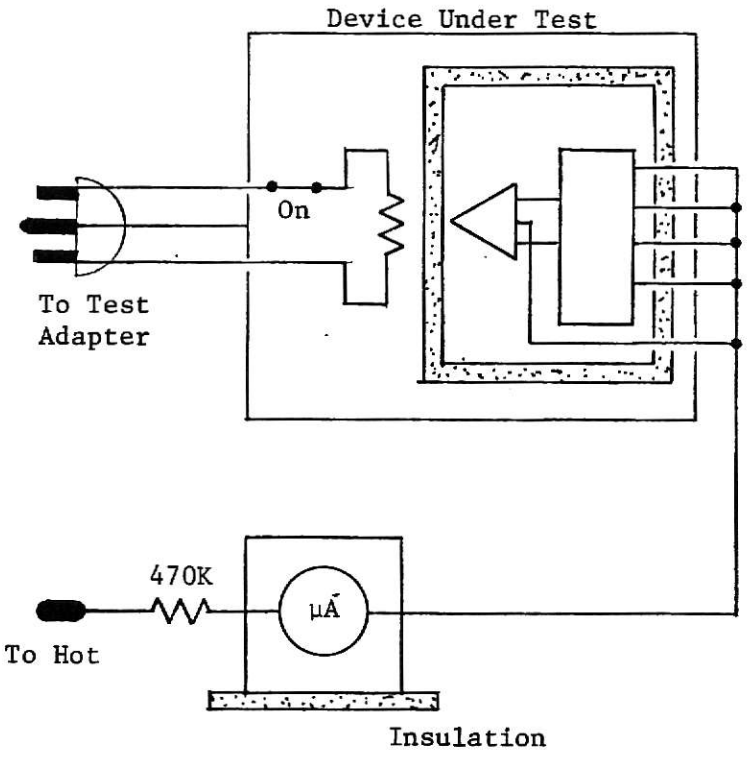

Fig. 3.9a. Meter Floating.

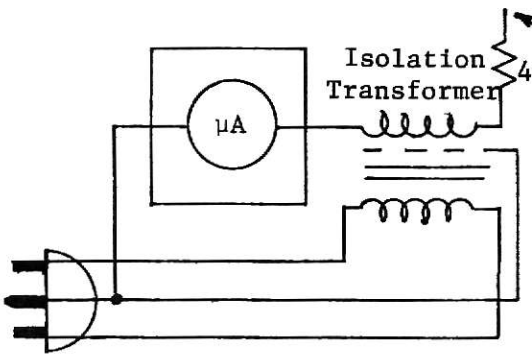

Fig. 3.9b. Meter Grounded.

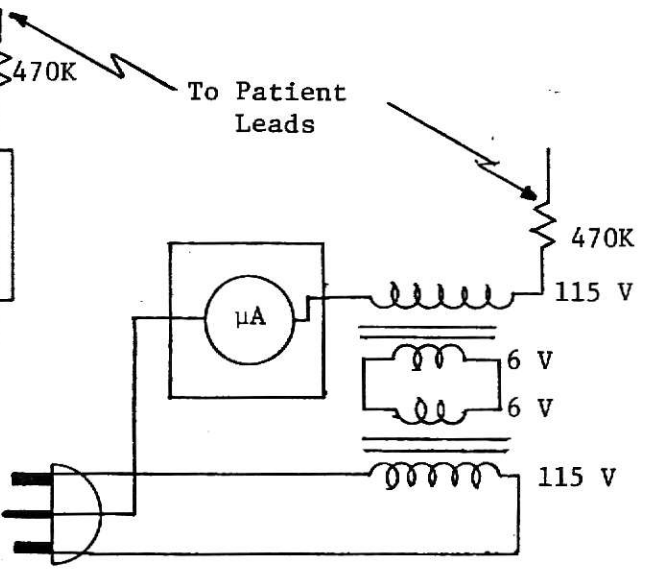

Fig. 3.9c. Improvised Isolation Transformer

Fig. 3.9. Test 4.

DUT: on, Polarity: normal, Ground: grounded.

Capacitance between patient leads and grounded objects can affect this measurement. Care should be taken to keep the patient cable away from such objects. It may be necessary to first disconnect the patient cable from the device and determine the increase in current upon reconnection.

Interpretation

Test 4 determines if the DUT has isolated input amplifiers. In that case, current into the patient leads with the externally applied voltage should be less than 20 μA. In devices without isolated leads, the current will be primarily limited by the 470K ohm resistor in series with the voltage source to about 250 μA.

The current measured in this test should be recorded and compared with previous values. Again, small variations may result from daily variations in atmospheric conditions and surroundings. Any substantial increases may indicate the beginnings of breakdown of amplifier insulation, for example, due to dust or oil buildup, and should be pursued further.

The relative simplicity of this set of procedures for application to preventive maintenance should be apparent from the summary found in Table 3.1.

It will be difficult or impossible to measure leakage currents on certain energy-emitting devices while they are in operational modes. This includes defibrillators, electrosurgical sources, and some ultrasonic equipment. Their energy output can overload the meter even in proximity with no direct connection. No attempt should be made to measure the leakage current of an electrosurgical machine in operation. Leakage should be measured in the standby mode only. Defibrillators should be checked in the charging mode,

Test/ Measurement	Circuit	Device Under Test	Ground	Polarity	Normal Reading or Relation of Readings	Interpretations of Abnormal Readings
1.1 1.2	Fig. 3.5	Off "	Open "	Normal Reverse	1.2 larger than 1.1	ON-OFF switch in neutral rather than hot lead.
1.3 1.4	Fig. 3.5	On "	Open "	Normal Reverse	1.4 larger than 1.3, the chassis leakage current, which should be less than 100 μA (less than 500 μA for Type B). Record M1.3	Equipment wired contrary to good practice.
1.5	Fig. 3.5	On	Grounded	Normal	Zero	Ground open in line cord or in DUT.
2.1	Fig. 3.7	On	Open	Normal	Less than 10 μA (less than 50 μA for Type B)	Reading the same as 1.3 indicates grounded RL lead; smaller reading, an isolated input.
2.2	Fig. 3.7	On	Grounded	Normal	Zero or less than 10 μA	Zero indicates grounded RL lead; small nonzero reading indicates an isolated input to be verified in Test 4.
3.1 thru 3.2 or 3.4	Fig. 3.8	On	Grounded	Normal	All less than 10 μA	Defective isolation or input amplifier.
4	Fig. 3.9	On	Grounded	Normal	Less than 20 μA	Larger reading indicates faulty insulation in isolated input or an amplifier with grounded RL lead.

Table 3.1. Summary of Electrical Safety Test Procedure.

but not during discharge. Attempts to measure leakage on such devices while they are emitting energy can result in serious injury to the meter, the operator, or both.

None of the above current or grounding resistance tests should be made when a patient is directly or indirectly in contact with the device under test. This is a necessary precaution, because some of the test configurations may introduce hazards.

Finally, one should take note that the current levels and standards quoted are based on judgement of several proposed standards. In general, none of these standards are official or mandatory on a regional or national basis. Research is continuing and changes are being considered at the time of this writing. Therefore, one must keep abreast of changes and alter these procedures accordingly.

Protection against electrical hazards by grounding of equipment is effective only as long as the integrity of the circuit from the device to the building ground is maintained at all times. This means that the entire system must be checked periodically to assure the ground path to be not only continuous, but of low resistance and reasonably equipotential throughout.

In addition to the ground circuit of the power distribution system, patient areas for the electrically susceptible should be provided with a redundant "Equipotential Grounding System." Each such patient will be referenced to one and only one "ground" and all power sources supplying that area shall be tied through the reference ground. While NFPA's 76B-T is being revised, the grounding systems described in it will be an adequate model for this discussion. However, there are likely to be changes in this area, also. If so, these procedures may need to be altered.

New installations and grounding systems that have not been regularly maintained should be tested to see that potential differences within the system are within limits. A precision millivoltmeter or one of the previously mentioned commercial test systems can be used for this test. The test should be repeated randomly, or staff permitting, regularly thereafter.

New and previously undermaintained systems should also be checked for acceptable resistance levels at various points within the system. These levels should be so low as to require "four terminal" measurements available with some commercial analyzers. This test should be repeated regularly within the PM schedule. If staff time permits, potential measurements might be made on the same schedule. However, on the first inspection, the resistance measurements should be preceeded by the potential measurements. If large differences exist, the small resistances will be difficult to measure accurately (10).

Several test devices and procedures also offer the option of testing ground integrity by injecting large currents on the ground line and detecting the voltage drop in the ground-neutral loop. There is sound basis for this technique in that weakened grounds may show themselves by failing under this stress. But, there is an added hazard. The high current injected will cause marked voltage drops along the ground line. These may be large enough to jeopardize patients. Unusual wiring, particularly in hospitals that have been expanded or rewired may carry this current to unexpected places. For this reason, high-current integrity tests should be performed only by persons well acquainted with the wiring distribution of the hospital and the hazards of the method (9).

One of the weakest links in grounding circuits is the connection between the equipment plug ground pin and the receptacle contacts. Because it varies with the specific combination of device and receptacle, and with positioning, resistance is not the best indicator of reliability at this point. Rather, the force required to withdraw a standard ground pin is generally used (7). Several inexpensive balances are available for this test, which should be repeated with the resistance tests.

The following are suggested standards to be met by new wiring installations before acceptance, or by previously undermaintained systems, and at reasonably frequent intervals thereafter: (13)

1. The potential difference between the following combinations shall not exceed 10 millivolts:
    a. Between any pair of ground poles of power receptacles in the same patient vicinity, whether energized or not.
    b. Between ground poles of an equipotential grounding system.
    c. Between ground poles of any receptacle and any equipotential system serving the same vicinity.
2. The potential difference between the following combinations shall not exceed 100 millivolts:
    a. Between the exposed conducting surfaces of fixed equipment served from the same distribution panel.
    b. Between the ground pole of an equipotential system and any accessible conducting surface in the same patient vicinity.
3. The potential difference between the following combinations shall not exceed 500 millivolts:

a. Between any power receptacle ground pole and the ground system of fixed equipment in the same patient vicinity but served from a different distribution panel.

b. Between ground systems and exposed conducting surfaces (except where there is an equipotential system as noted above).

The following are suggested standards to be met by new or previously undermaintained systems and at regularly scheduled intervals thereafter:

1. The following resistances shall not exceed 0.1 ohm: (13)
   a. The resistance between any pair of receptacle ground poles serving the same patient vicinity.
   b. The resistance in an equipotential system between the patient bonding point and any exposed conducting surface bonded to that point or between that bonding point and the ground pole of any receptacle serving the same vicinity.
2. The resistance between a receptacle ground pole and the ground pole of a receptacle fed by a different circuit from the same distribution panel shall not exceed 0.5 ohm.
3. The resistance between a receptacle ground and exposed conducting surfaces of fixed equipment served from the same distribution panel shall not exceed 0.5 ohm.
4. The resistance between a receptacle ground and exposed conducting surfaces of fixed equipment in the same patient vicinity but fed from a different distribution panel shall not exceed 1.0 ohm.
5. The tension required to remove a standard test pin from a receptacle ground pole should not be less than 10 ounces (14).

Inspections of power system grounds and equipotential grounding system in the same vicinity should be done at the same time in the PM schedule. Less stringent requirements may be applicable to corridors and similar areas where patients are unlikely to spend much time. However, employees deserve protection also, therefore such areas should not be ignored.

It has been shown that the tension in a receptacle ground pole will decrease with heavy use, especially frequent insertions and abusive treatment. When these receptacles are replaced, they should be saved and retested at a later date. With time, the contacts may relax to the point of being acceptable for low-use, non-critical areas. Also, contact tension will show a marked decrease, even in Hospital Grade connectors, when an appliance is left plugged into it for extended periods of time (e.g., monitors in ICU/CCU). Therefore, it is good practice to plug such devices into different receptacles from time to time (15).

Other approaches to electrical safety are frequently under discussion, notably, the use of isolated power systems. It must be understood, however, that investing in more hardware is not a substitute for maintenance. Quite the contrary, <u>any</u> piece of equipment must be maintained in order to be relied upon. It is felt that if equipment is carefully selected and then maintained with a program similar to the one described herein, safety can more than adequately be achieved. In a few cases and selected locations, more measures will be required. These must be in addition to, not instead of adequate maintenance efforts.

IV. PREVENTIVE MAINTENANCE: A Model for Implementation

4.1 Overview

An effective preventive maintenance program will generally consist of four major parts:

a. An Inventory File of identification, brief data, and a record of work done on each piece of equipment;

b. A Data File of all available information concerning specifications, operation, and maintenance of each device;

c. A Procedures Manual including lists of the tests and inspection points that constitute the PM routine for each device;

d. A Control file used to keep track of scheduled inspections.

4.2 Inventory

The first step in establishing a PM program is to determine which equipment shall be included. A detailed inventory will aid in this decision and provide necessary data at the same time. A form similar to Figure 4.1 may be used. Much of the basic identification may be obtained from the hospitals asset inventory. This approach will save considerable time by providing a list of items to be sought. Each data sheet should then be completed after a thorough inspection of each piece of equipment, preferably at its site of use.

In addition to an inventory tour to complete forms on listed devices, a tour must be made to find those that were previously unlisted. This is especially true of mechanical equipment. Many air conditioners, pumps, etc. that were part of the original building contracts will likely not be listed as separate assets.

EQUIPMENT MAINTENANCE SURVEY
MEMORIAL HOSPITAL, MANHATTAN, KANSAS

Date	Description			Control Number
Manufacturer			Fixed ☐ or Mobile ☐	Location
Address of Manufacturer				Model Serial
Date Accepted	Installed	Purchase Order #	Depreciation Rate	Cost
Vendor			Warranty or Special Terms	
Service			Waiting Time	
Parts			Delivery Time	
Volts / Hz	Amps / Watts	HP / Phase	PM Intervals / Procedures	
Other Data			M _____/_____ Q _____/_____ SA _____/_____ A _____/_____ Other _____/_____	
Can Load Be Shed More Often or in Emergency?			Present Duty	
Emergency Power? No ☐; Critical ☐; Safety ☐; Support ☐			Patient Type: A ☐; B ☐; C ☐	
User Remarks				
Inspector Remarks				
	Inspector			

Fig. 4.1. Inventory Survey Form.

Each piece should be labeled with its Control Number (CN) as it is inventoried. Once this number is assigned, it will be the key to cross-referencing through all sources of information concerning the device it identifies. At Memorial Hospital, asset inventory numbers are also used as Control Numbers. Many larger hospitals use CN's that form location codes for the identified devices. While this is a virtual necessity for large operations, it may tend to hinder the smaller ones. In the small hospital, equipment is frequently moved to where it is needed at the moment. A location should be assigned to each item for times it isn't in use. To use this for identification, however, will be of questionable benefit. Instead, asset inventory numbers serve at least as well to identify pieces. This minimizes the number of codes needed to specify a device. Establishing computer files or processing the Control File by hand will be expedited by having all CN's of similar format.

The accounting office of Memorial Hospital is cooperating by reserving a block of inventory tags to be used on fixed equipment and other pieces that are not yet listed and would not ordinarily be a part of the asset inventory. A special concern will be scheduling electric receptacles to be checked for grounding and polarity. These will be identified by their location on simple floor plans. Various areas such as third floor hall, second floor patient rooms, etc. will be assigned Control Numbers. The numbers will then be used in scheduling inspections and keeping records.

Looking at the rest of the survey form, Figure 4.1:

Fixed/Mobile - frequently moved devices will generally need to be inspected more often.

Data Accepted - the date a device was approved as operating to the hospital's satisfaction. This should be about the same as the date of final payment. The date of installation is also noted.

Depreciation rate - this along with the original cost and costs listed in the maintenance record will give clues as to when a device is near the end of its productive life.

Vendor, Service, and Parts - addresses and phone numbers of principle sources.

Volts/Hz, Amps/Watts, Phase/HP, and Other Data - items that may assist in further identifying a device, especially for ordering replacement parts.

PM Interval/Procedure - the frequency at which the device should be inspected and the identifying number of the procedure to be used. These blanks will need to be left open until the PM Manual is prepared.

Can Load Be Shed, and Present Duty - The data gathered with these two questions will aid in making decisions about energy economy and conservation. How much of the time is the device presently powered up? How often and when can this duty cycle be reduced, either to conserve energy or in the event of an emergency such as a brown-out or power failure?

On Emergency Power? - Is this device ordinarily connected to the hospital's Emergency Power System? If so, according to the definitions, in the National Electrical Code, article 517, should it be on a Critical, Life Safety, or Life Support branch?

Patient Type - the criterion of electrical safety the device must meet in its normal use. Types A and B are defined in the previous chapter. Type C is equipment that seldom, if ever would be contacted by a patient.

User and Inspector Remarks - These are a very important part of the survey, not merely for the information they provide, but for diplomatic reasons as well. The persons most familiar with the condition of a device should be those using it regularly. It is important for them to feel that an active interest is taken in the reliability of their tools. This survey can be used to acquaint them with the new PM program and encourage them to notify the proper persons of changes in equipment status before a device fails altogether. The inspector should translate the user's evaluation of a device into technically meaningful data. This data will give a clue as to how well a device meets the user's needs, if it is being correctly used, or if a different device would be more appropriate.

As the survey forms are completed, the information should be transferred to a Maintenance Inventory card, Figure 4.2. This card is designed to be kept in a Visarecord, Kardex, or similar flipcard file. These cards will be arranged alphabetically by device description. Within a given description, the cards will be placed in the order of the CN's. Care should be taken in choosing descriptive titles. All similar items should carry the same title. Each entry in the PM system (e.g., in the Data File discussed later) that refers to a given device should carry precisely the same description.

Once the inventory cards have been filed, the Survey forms will become cover pages for their respective data files. Space may be provided on the reverse side of the Survey forms for additional remarks to be compiled during the history of the device. Also, a list of descriptions and stock numbers of commonly used replacement parts and expendable accessories can be kept on the reverse side for quick reference.

MEMORIAL HOSPITAL EQUIPMENT MAINTENANCE INVENTORY			
Manufacturer			Rep. Phone
Model	Serial		Service Manual
			Instruc. Manual
Vendor		Phone	Cost
			P.O. #
Service			Phone
Parts			Phone
Received	Installed		By Whom
Warranty			PM Procedure(s)
Emergency Power		Patient Type	PM Frequency
No☐ Critical☐ Safety☐ Support☐		A☐ B☐ C☐	M Q SA A Other
Location	Description		Control Number

Fig. 4.2. Inventory Card.

Also located in the inventory card file are the Work Record cards, Figure 4.3. Each device's work record is inserted in the space under the back of the preceeding inventory card. That way, when the file is opened to a given inventory item, its respective work record will be visible immediately above it. When a record card is full, it is attached to the corresponding survey-cover sheet in the Data File.

4.3 Data

An inventory entry contains rather brief data about a device. The corresponding Data File entry contains virtually all in-house knowledge of that device. Among the types of information to be kept in a data file are:

1. Survey form - cover sheet
2. User's manuals
3. Maintenance and troubleshooting manuals
4. Technical specifications and schematic diagrams
5. Performance records and logs of safety inspections
6. Work and cost records
7. Names and addresses of sources of parts, service, and manufacturer representation
8. Any other data of reasonable concern in operating and maintaining the device.

Generally, there will be only one data file for each type of device. For example, if the hospital has five cardiac monitors of the same make and model, differing only in serial number and minor modification, they will all be referenced to the same data file. Multiple copies of technical materials should be kept, even for unique devices. One copy resides in the Data File and the rest are to be stored in a safe place as replacements in the event

WORK RECORD				Control Number			
Date	PM/CM	Description	Hours	Time	Parts	Other	Total
12/3/74	P	327	1.5	4.50	—	—	4.50
2/5/7	P	327	1.25	3.75	—	—	3.75
3/19/75	C	Replace Broken Caster	.75	2.25	4.58	—	6.83
5/2/75	P	327	1.25	3.75	—	—	3.75

Fig. 4.3. Work Record Card.

of loss or wear to the file copies. Additional user manuals are kept with the devices as needed.

The technical manuals for some devices may be several large volumes. Therefore, a "file" may consist of several folders in order to contain them all. These files are kept in standard folders in a vertical file cabinet. They are filed sequentially by Control Number. If a file consists of more than one folder, they all bear the same CN.

In the case of several devices of the same type, the data is kept in the file under the lowest CN assigned to any of the like pieces. For each of the other like items, a file tab is marked with its Control Number and the legend: "See File (CN)." This folder is filed in proper sequence. It will contain little more than the Survey-cover sheet and back work records pertaining to that particular device.

Two sets of files have now been established. The Inventory File is ordered alphabetically by device description. The Data File is ordered sequentially by CN. Two indexes would now be prepared: One to match descriptions with each listed number and on to list the Control Numbers that apply to each description. Copies of these indexes should be placed at the head of both sets of files and in the PM Manual.

4.4 Preventive Maintenance Manual

The PM Manual is assembled in a loose-leaf ring binder or similar book that may be readily altered. It is the instructional tool within the PM system.

The manual contains three sections. The first sets out the general philosophy and structure of the PM system. In other words, it summarizes the material presented here. The next section outlines how the system

meshes with other operations of the hospital. Specifically, procedures are given for scheduling inspections in cases where normal hospital functions might be disrupted. Procedures are also given for removing a device from service for safety or other reasons. The bulk of the PM Manual is inspection procedures. PM employees are to use the manual to be sure that none of the checkpoints are overlooked. If the regular inspector is absent for holidays, vacation or sick leave, any qualified maintenance employee should be able to take his place, using the PM Manual.

The final version of the PM Manual is assembled after the Inventory and Data Files are completed. The procedures are written taking into account manufacturers' recommendations, use of the device in the local situation, past experience, and future expectations. Experience with the PM program will, undoubtedly, cause alteration of some procedures. This is especially true of the inspection intervals that are originally chosen.

One procedure may apply to a single model of device or to several similar ones. The sample page shown in Figure 4.4 is for a specific model of cardiac monitor of which Memorial Hospital has three. The procedure is Figure 4.5 is more general for belt-drive fan assemblies. It applies to about ten units at Memorial Hospital that are similar, but not necessarily of the same make or model.

Procedures may be ordered within the manual alphabetically by titles that correspond to those used in the Inventory. Alternately, they may be ordered according to the PM Procedure Number which is the lowest Control Number of a device to which the procedure is applicable. In either case, the Manual should be thoroughly indexed to facilitate finding the desired pages. The manual should also contain copies of the cross-reference indexes of the Inventory and Data Files.

Procedure 3___

Applies to Control Numbers:

3_____
3_____
3_____

Zenith Display Scopies with Mod 5A 808 Preamps

Monthly:

1) General mechanical integrity - Check for cleanliness and workability. Give special attention to controls, readouts, and strain reliefs.

2) Leakage current - Perform routine leakage and ground integrity series.

   Type A: Chassis less than 100 μA
   Leads less than 10 μA
   Ground less than 0.1 ohm

3) Electrical function - Check the response to all controls using internal calibrator.

4) Clean all exposed parts.

Semiannual: In addition to the above, the following should be every 6 months.

5) Overall Gain - Check for degradation. Nominally 54 db.

6) Calibrator, 1mV - Verify to ±2%.

7) D. C. Balance - Maximum offset output as REMOTE connector, ±40mV.

8) Common Mode Rejection Ration (CMRR) - Greater than 77db.

9) Frequency response - For 1 mV signal input:

   MONitor mode: 3db down with respect to 2 Hz between 0.4 and 0.7 Hz and between 30 and 50 Hz.
   DIAGnostic mode: 3db down with respect to 15 Hz between 0.4 and 0.7 Hz and above 200 Hz.

For detailed procedures, see "Performance Standards" in maintenance manuals for Zenith 808 Display Scope and Mod 5A preamplifier.

Fig. 4.4. Sample PM Procedure Manual Page

Procedure 3___

Applies to Control Numbers:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Exhaust and Supply Fan and Motor Assemblies

Monthly:

1) Oil Motor - Apply 3 or 4 drops of S.A.E. 30 wt. oil to each oil cup.

2) Check Belts

3) Wipe Clean

4) Inspect - Visually and Aurally

Annually:

5) Clean Assembly with Koilex

Figure 4.5 Sample PM Procedure Manual Page.

Several copies of the PM Manual will be desirable. The master copy should be clean black copy on sturdy white paper. It should not circulate for general use. Working copies should be photocopied or otherwise duplicated from the original. As pages of the working copies of the manual are lost or damanged, they can be readily replaced by copying from the master. Since this system covers both plant and medical equipment, it may be chosen to keep one full working copy and several partial copies. These partial copies might be selected as "Electrical/Electronic" and "Mechanical," selected by building or area, or whatever fits the manner in which the work load is assigned.

4.5 Scheduling and Recordkeeping

The information required to organize a preventive maintenance program has been gathered and collated. Now the ongoing task becomes the scheduling of inspections, recording the results and keeping all files current. Two approaches to this task are described in the following. One is to perform all of the required clerical work manually. The other is to use computers or Electronic Data Processing (EDP). Each have their advantages but are not exclusive of each other.

The basic calendar and work schedule will first be laid out as for manual processing. This is the Control File of the PM system. It is inadvisable to attempt to computerize this portion of the system without first going through the manual version. The manual charting of the calendar provides an overview of the work load and should smooth the transition to EDP. Likewise, a PM system should not be established under the assumption that it will never be computerized. The information-gathering techniques presented here provide a format that is compatible with either the manual or computerized system.

The first step in establishing a schedule for PM is to determine how many items with each type of interval there are. In general, four or five intervals are involved: biweekly, monthly, quarterly, semiannual, and annual. A few items will require odd or irregular intervals. Initially, the interval for each item is determined at the time its procedure is written. After a few cycles of the PM intervals, they may be adjusted as needed. With some exceptions, the intervals should be adjusted to achieve a five percent failure rate. That is, the need for adjustments, calibrations, or corrective maintenance should be found in about 5% of all inspections of a given area or type of device. Certain critical areas such as ICU/CCU, surgery suites, and the Emergency Department come under a 1% failure rate criterion.

Care must be taken not to be too eager to shift the selected interval in the first year or so of PM. If the equipment involved hasn't been under regular maintenance, it is expected to have a very high rate of failure during the first few intervals. Also, in a small hospital, the sample space of most types of devices will be small enough to make the statistics deceptive. However, tempered with experience and judgement, the criterion should be useful.

Once the quantities and types of intervals have been determined, a trial fit to a calendar is taken. To fit the calendar, an estimate of the labor time required for each inspection must be made. Next, it must be decided which inspections should be grouped by device type and which should be grouped by common locations.

The calendar fit is made on thirteen-column ledger pages. One column is used for each month (Figure 4.6). Within each major column, five columns are assigned, one for each of four weeks of a month and one for the month total. The thirteenth major column is for year totals. Each inspection or

MEMORIAL HOSPITAL
PREVENTIVE MAINTENANCE SYSTEM
WORK LOAD DISTRIBUTION

EXAMPLE TRIAL FIT

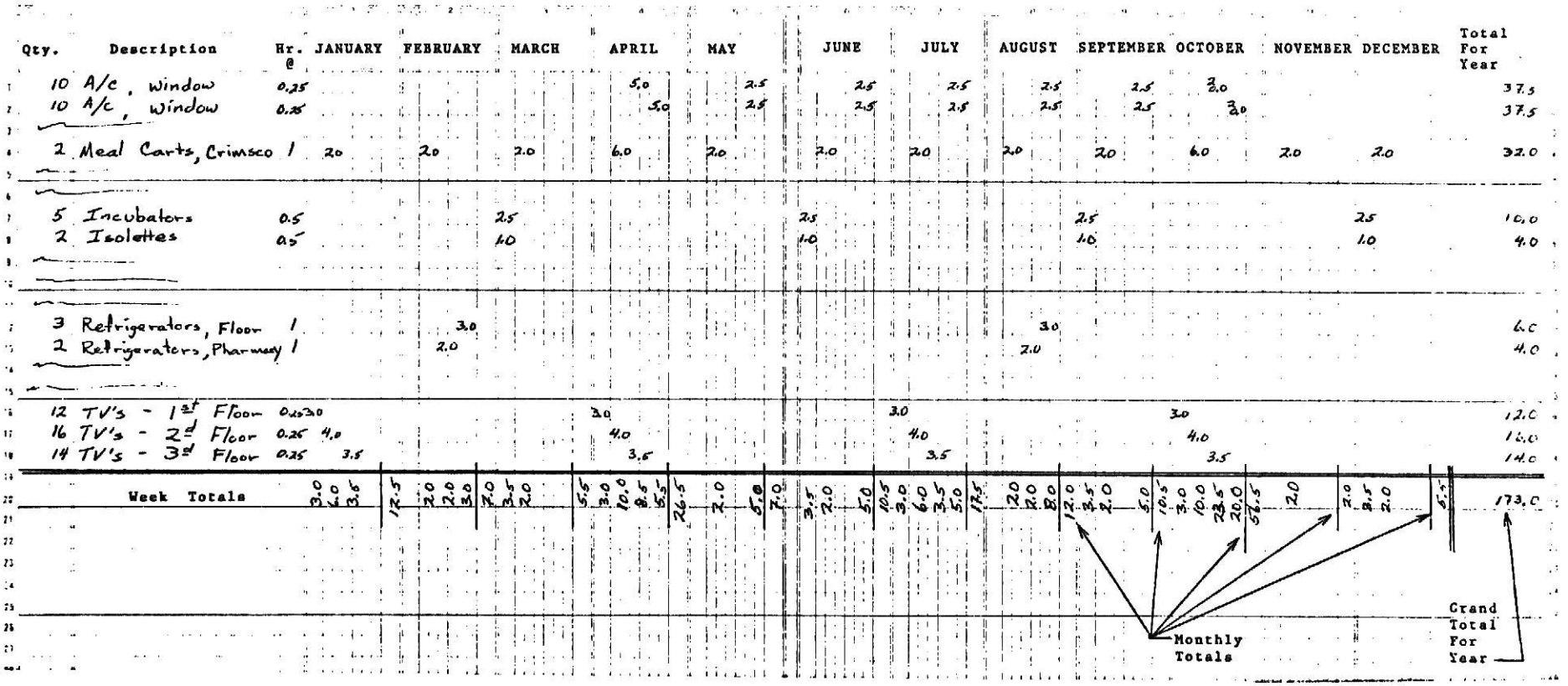

Fig. 4.6. Example: PM Schedule Trial Fit to Calendar

group of inspections is listed under "Description." The expected labor time is listed during the week in which the inspections are to be done. When all items have been recorded, the labor totals for each week, month, and item can be determined. Several trial fits will probably be necessary to achieve an even work distribution throughout the weeks. Just as PM intervals must be adjusted, so the calendar of job assignments will need to be revised as a more accurate picture of the time requirement develops.

To implement the PM schedule manually, a simple calendar page is used (Figure 4.7). Note that items are only scheduled as to a given week, not down to the day. This should give adequate flexibility for use of personnel and fitting in unexpected jobs. By scheduling only four even weeks to a month, four additional weeks are left open through the year to help catch up with the schedule when needed.

This control calendar is drawn in clear black copy on white paper, one quarter per page. Then working copies are photocopied from it. Each week, the person responsible for the Control File simply writes work orders for those items that are due that week. The necessary procedures, forms and other information can be located through the Control Numbers by this person or by the worker to whom the job is assigned.

When the PM inspections for the week are completed and the results recorded in the appropriate logs or records, the work orders are to be signed by the inspector and returned for posting in the work records. Enough information should be noted on the work order to allow it to be posted in the proper work record. When an inspection has been completely posted, a line is drawn through its Control Number on the working calendar with a brightly colored pen. Thus it is easy to determine the present status of the work schedule and if any work was missed.

MEMORIAL HOSPITAL
PREVENTIVE MAINTENANCE SCHEDULE
1ST QUARTER

WEEK 1	WEEK 2	WEEK 3	WEEK 4	
2271 M 2352 M 148 Q 156 Q	.....	1378 M 1379 M	1479 M ..... 1484 Q	JANUARY
.... 1694 Q 1698 Q 1678 Q 3105 Q	....	1378 M 1379 Q	.... 4752 S 938 S 623 A	FEBRUARY
....	2540 M 2542 M 2543 M ..... 2544 Q	.... 2548 M 2549 M 2550 M	2556 M 2557 Q 2559 S .... 3102 S 4101 A	MARCH
1	2	3	4	

Fig. 4.7. Example: PM Schedule Manual Calendar.

4.6 Electronic Data Processing

Rapid advances in technology and an aggressively competitive market will soon make computers accessible to even the smallest of hospitals. Small, high capacity minicomputers that will handle most or all of a hospital's computing needs are already available at declining prices. The use of a computer to perform many of the clerical chores of a preventive maintenance system will relieve a major share of the paperwork from the maintenance staff. This is especially true for the small hospital in which the maintenance staff consists of one to three persons with no clerical assistance.

A considerable amount of time will be required to initially computerize the PM system. Once this is accomplished, however, it should be possible to do a week's scheduling, posting, and file updating in a half day or less. Further, on an interactive terminal system, an administrative secretary or similar personnel can be readily trained to do this work.

In order to implement this PM system on computer, the machine and software must provide capabilities for filehandling between main frame and peripheral long term storage. String variable manipulation is also required. In the case of Memorial Hospital, the system will be implemented at Kansas State University's Department of Electrical Engineering. The computer is a Data General NOVA 1200 with two disks, cathode ray terminal, paper and magnetic tape input/output (I/O), and teletype I/O. The programming will be done primarily in Extended BASIC.

The program structure will consist of a number of special-purpose subroutines organized and called through a central program. In addition to the central program and a routine to create files, the system can be initiated with a scheduling routine and a routine for posting completed work.

A skeleton flow chart of the central program is shown in Chart 4.1. It essentially has two functions. It allows the various routines of the system to be called and executed as needed, and it keeps a log of the use of the system. The rest of the program will be the various routines which are, themselves, to be written in subroutine structure. As a result, functions may be added to or altered within the program without uprooting major portions around them.

Most of the program will be based on handling each device's Inventory File as a data block. A sample of the output for a device file is shown in Figure 4.8. The files will be created and called under file names corresponding to the Control Numbers. Most of the data in the upper portion of the form will be in string-variable form. All of it can be obtained directly from either the Inventory File or Survey sheets. Each column under the Work Record will be either a variable or string-variable.

Chart 4.2 is a flowchart of the Scheduling routine. When the operator requests a schedule of PM work to be ordered for the next week, the routine will first request the date of the day ending that week. A perpetual calendar subroutine will compare that date against the date of the last recorded PM date in the Work Record (the last nonzero date for which PM/CM = P). If the calculated elapsed time is equal to or greater than the stated PM Interval (INTRVL), a subroutine will be called to write a work order on the device. If the elasped time is less than INTRVL, the file will be set aside and the next file will be examined in the same manner.

It would seem simpler to merely store a lookup table for each week, similar to Figure 4.7. However, that approach would merely write orders for items normally scheduled that week. The approach outlined above will continue to reschedule an inspection that was missed until it is recorded as completed.

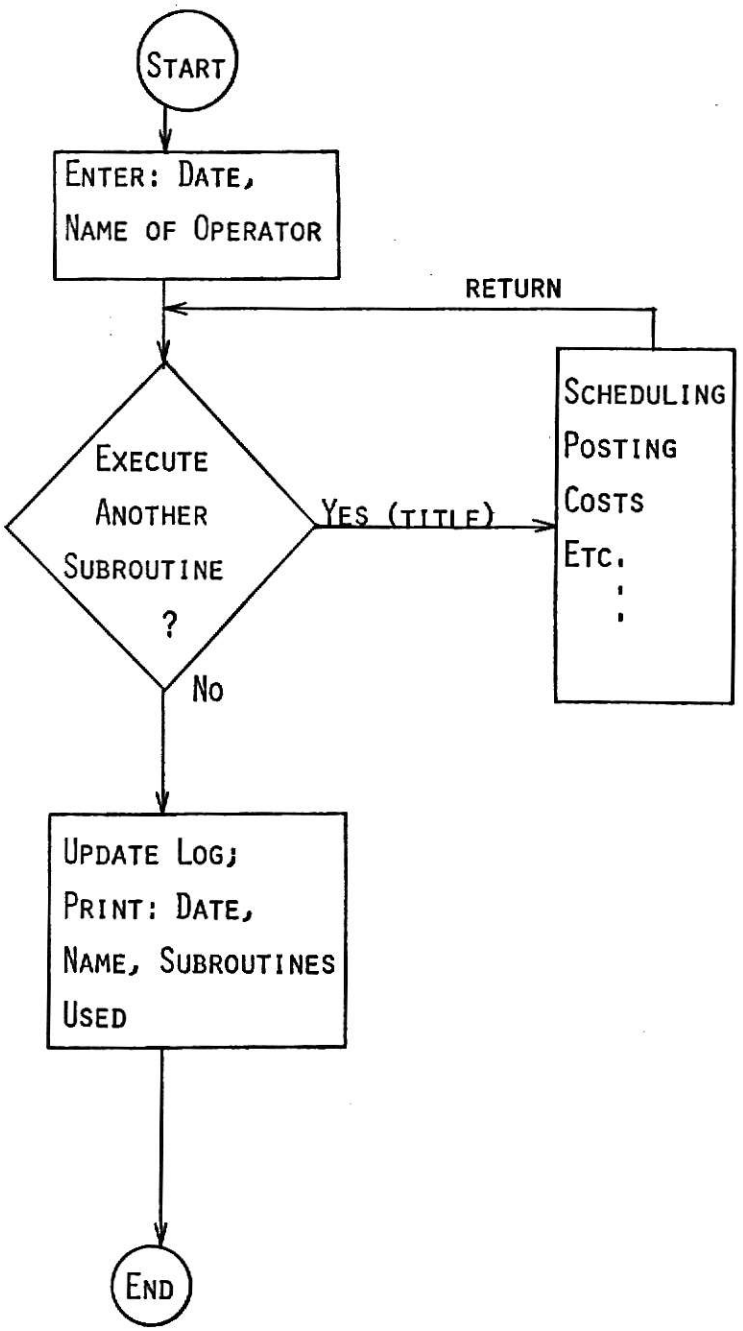

Chart 4.1. Master Program.

MEMORIAL HOSPITAL PREVENTIVE MAINTENANCE SYSTEM

FILE: control number DATE: of this interaction

TITLE: device description LOCATION: where normally kept

MANUF: name of manufacturer

MODEL: number SERIAL: number PROCEDURE: number

SAME: Control Numbers of devices of same make and model

ACCEPT: date paid for INSTLD: Date installed INTRVL: PM interval

PONUM: purchase order number DEPRT: depreciation rate

COST: original cost

VENDOR: name

LDSHD: Load Shed - times device can be powered down

EMPWR: Emergency Power - "NO" or class

PATYP: Patient Type - A, B or C

WORK RECORD

DATE	PM/CM	DESCRIPTION	HRS	TIME	PARTS	OTHER	TOTAL
12 3 74	P	327	1.5	4.50	0	0	4.50
2 5 75	P	327	1.25	3.75	0	0	3.75
3 19 75	C	RPLC BROKEN CASTER	.75	2.25	4.58	0	6.85
5 2 75	P	327	1.25	3.75	0	0	3.75

Fig. 4.8 Example Computer File.

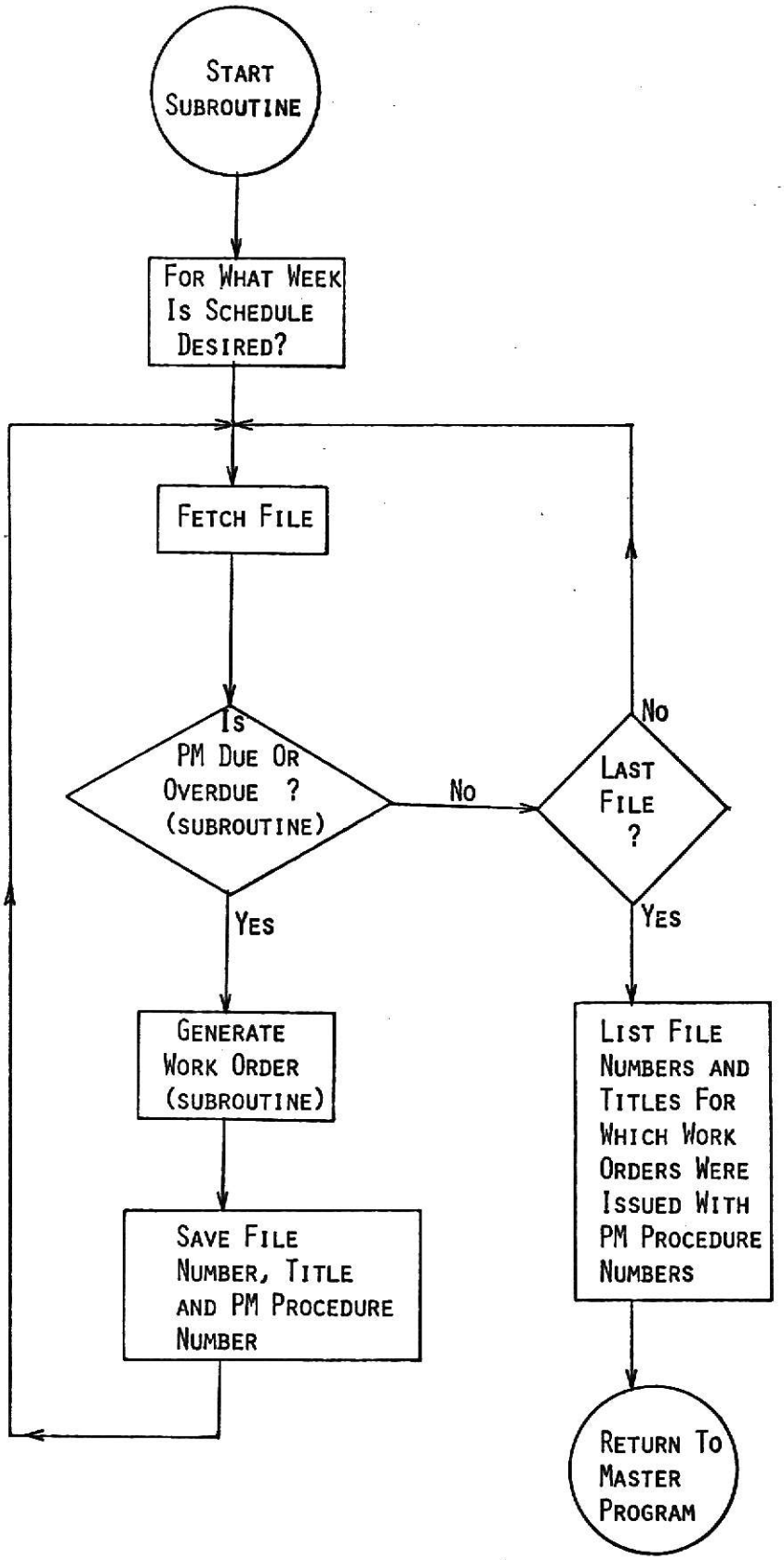

Chart 4.2. Scheduling Routine.

When the last file has been examined, a list will be printed. This list will give the file name (CN), device description, and appropriate PM Procedure Number of each item for which a work order was issued. This list can be used to verify the work load and to quickly locate the procedures and forms needed for that week. The system will then return to the central program.

A flowchart of the Posting routine is shown in Chart 4.3. Work orders generated by the previous routine will contain space for the inspector to note any information needed by the operator to update files as to PM work completed during the previous week. The operator should also have available the completed work orders from corrective maintenance performed during the past week. The Control Number of the first item to be posted is fed to the routine. That file is fetched and a subroutine called to receive the new data and insert it into the file. When the last file has been updated, a zero given as a file name will return the system to the central program. As in the Scheduling routine, a list of all files updated will be generated. All posting of the previous week's work should be done before the next week's schedule is drawn or the previous week's schedule will be reported out as delinquent.

Once the system has been in operation for some time, other subroutines can be used to obtain many kinds of cost and performance comparisons from the Work Record. Since identifying data will be in string-variables form it will be possible to obtain listings by virtually any classification stored in the files.

The entire set of files can be written out in hardcopy periodically. This will provide an office copy of the administration's reference and for reference by accrediting agencies. A complete listing should also be taken periodically in hard input medium, such as paper or magnetic tape to provide system backup.

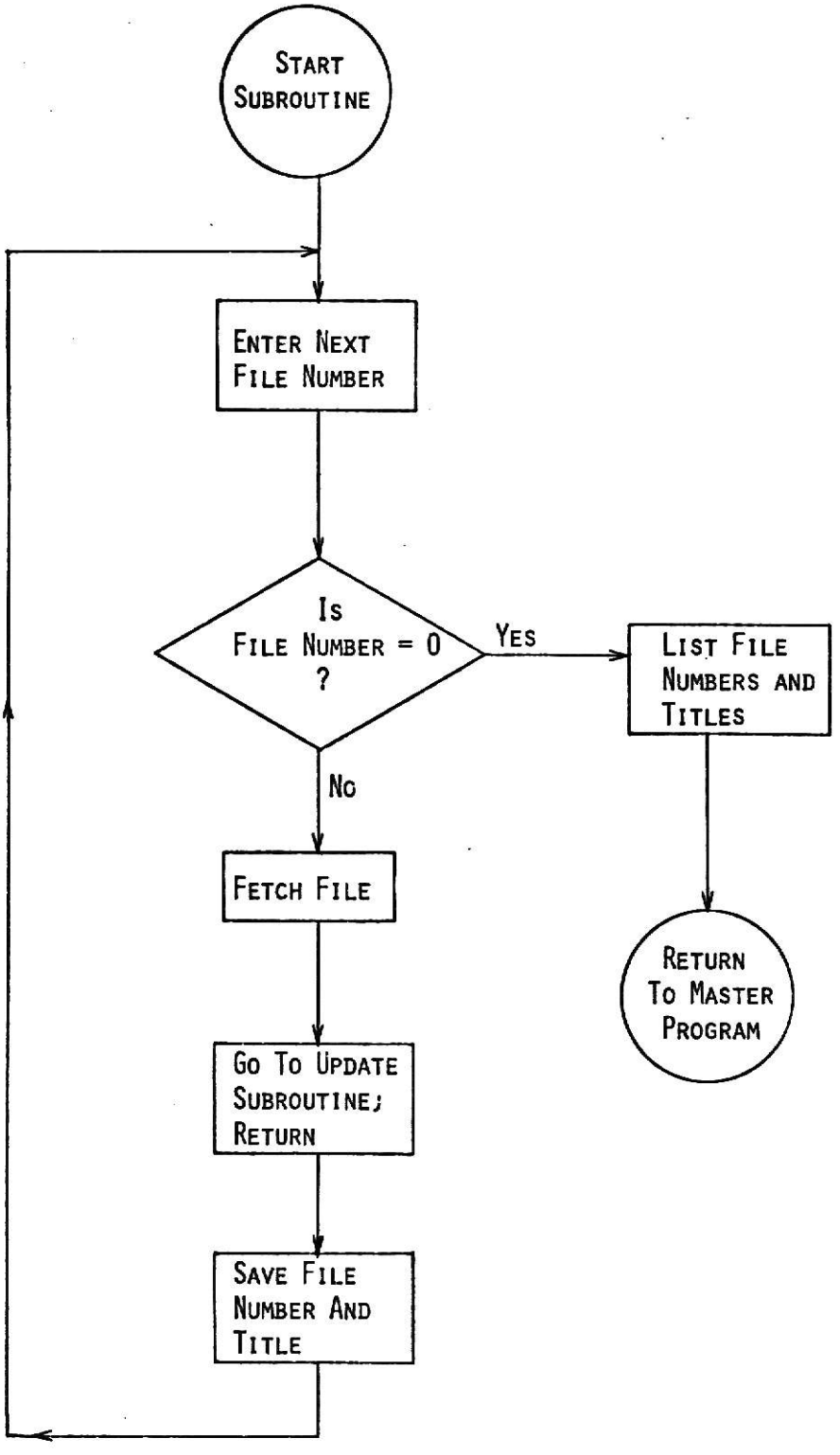

Chart 4.3. Posting Routine.

V. CONCLUSIONS AND RECOMMENDATIONS

This report has offered motivation for the application of preventive maintenance in the environment of health care facilities. Evidence has been presented that PM has definite economic advantages and serves to reduce a hospital's liability. PM can cater to the rights and peace of mind of both the patient and the hospital employee. In institutions dedicated to the maintenance of public health, it is not too much to ask that devices used be both reliable and safe.

Particular attention has been given to recommending methods of maintaining equipment in an electrically safe condition. Repeating, part of the methods recommended and indeed, the entire area of electrical safety are subject to controversy and change. The recommendations herein represent what is apparently the soundest immediate thinking. It behooves one to be prepared to change methods and thinking if solid new evidence supports such a change.

While there are many approaches to preventive maintenance, most can be summarized in a few basic steps:

- Inventory and determine what equipment is to be included in the PM program.
- Obtain and organize the necessary data on these devices.
- Establish inspection procedures and intervals for each piece.
- Assemble a preventive maintenance manual and complete the inventory and data sets.
- Assemble a control file and calendar for scheduling.
- Activate the PM system.

The goal, in all cases, is to give regular and well-documented attention to each piece of equipment. It will generally minimize confusion to activate a PM system only after it is entirely assembled as outlined above. However, equipment should not be neglected while paperwork is being organized.

At Memorial Hospital, mechanical equipment is already being regularly maintained, but documentation is sparse. The present effort will mesh well with the type of program presented here with only minor changes. Therefore, that portion of the PM system will continue to function while the documentation is organized by University personnel.

During the last JCAH inspection, it was stated that before the next inspection in December 1975, there must be documented reports as to the electrical safety and integrity of devices used in anesthetizing areas. In general, none of the patient care equipment has been regularly inspected for electrical safety. It is therefore recommended that while the Inventory Survey is being made, electrical safety inspections should be performed. First priority should be given to the surgical suite, delivery rooms, ICU/CCU, and the emergency department. These areas and general patient areas should continue to receive primary attention throughout the program.

While this PM system is being implemented at Memorial Hospital, the mechanical inspections will be conducted by hospital personnel. At least initially, most electrical inspections will be conducted by University personnel. In either case, PM personnel should be pulled from their assignments only in the case of emergency so that they can adhere to a regular schedule.

Finally, preventive maintenance will be most successful if it is not a function solely of maintenance personnel. Education of the entire staff can play an important part. Formal in-service education can be used to

acquaint them with the existence and function of the new system. Informally, when inspectors find problems that can be avoided by operator education, the opportunity should be taken to provide the needed instruction. The hospital staff who work with a device are in the best position to be familiar with its condition. Therefore, all contacts with the staff should be made with an attitude that will encourage them to call attention to changes in equipment condition and performance. They should also be encouraged to seek advice on methods of operating their equipment that will prolong its life and improve its results.

In closing, the system presented here is a basic structure. It is intended to be modified. At Memorial Hospital, time and experience will indicate what changes are needed. For other hospitals, it may need to be modified before implementation is begun. In whatever situation, the changes needed to improve it and better serve the total patient care system are encouraged.

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This report is dedicated to the welfare of the patients and patrons of Memorial Hospital, and, with special gratitude, to the memory of Dr. Dale E. Kaufman (1931-1975) for his friendship and guidance as a member of my graduate committee.

A PREVENTIVE MAINTENANCE AND ELECTRICAL SAFETY INSPECTION SYSTEM FOR A RURAL COMMUNITY SMALL HOSPITAL

by

STEPHEN CHARLES RICHARDS

B.A., Kansas Wesleyan, 1973

AN ABSTRACT OF A MASTER'S REPORT

submitted in partial fulfillment of the

requirements for the degree

MASTER OF SCIENCE

Department of Electrical Engineering

KANSAS STATE UNIVERSITY
Manhattan, Kansas

1975

ABSTRACT

Medical instrumentation and supporting equipment continues to rapidly increase in volume and sophistication. Accompanying this increase is the concern over the economics, reliability, and safety of the equipment.

An approach to preventive maintenance in the hospital is proposed. Special attention is given to the limited ability to operate such a system in a small non-research oriented hospital. A simplified procedure to evaluate the electrical safety of medical devices is included in the proposed system. An example of implementing a preventive maintenance system is discussed, including guidelines for computerizing the required bookkeeping.