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MARCH 1971
50¢

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NEVER UNDERESTIMATE THE POWER OF A WOMAN

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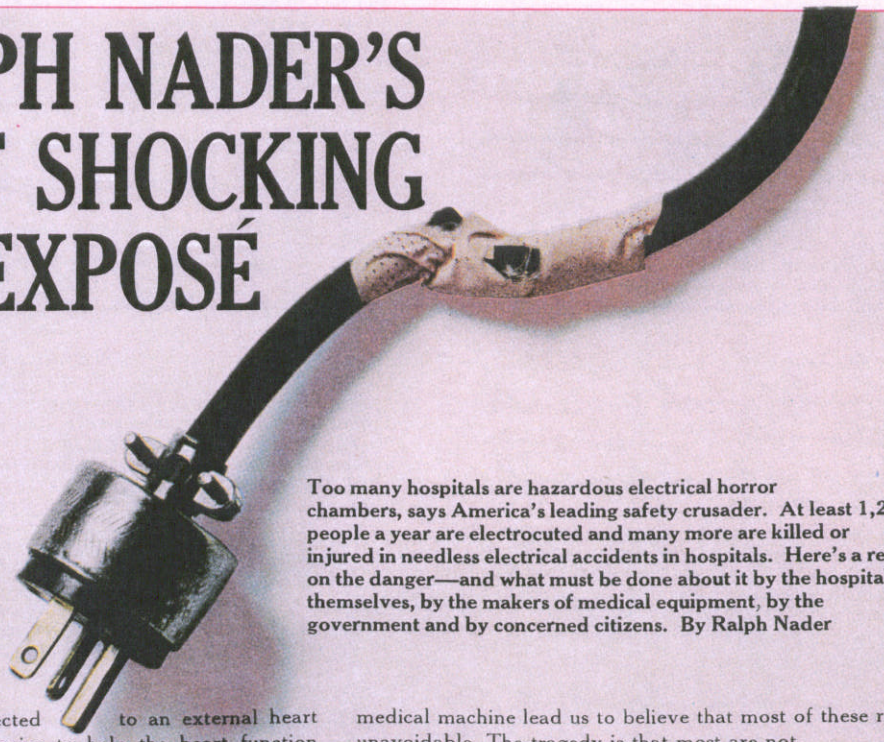
CHANGE OF ADDRESS: With service adjustment requests send latest mailing labels to Ladies' Home Journal Subscription Service, Flushing, New York 11357. Allow eight weeks for change. Postmaster: send form 3579 to same address.

RALPH NADER'S MOST SHOCKING EXPOSÉ



Too many hospitals are hazardous electrical horror chambers, says America's leading safety crusader. At least 1,200 people a year are electrocuted and many more are killed or injured in needless electrical accidents in hospitals. Here's a report on the danger—and what must be done about it by the hospitals themselves, by the makers of medical equipment, by the government and by concerned citizens. By Ralph Nader

Not long ago, a patient connected to an external heart pacemaker—an electronic device to help the heart function normally—was found dead, part of his body touching the metal frame of his electrically operated hospital bed.

In another hospital, a resident physician was discovered slumped lifeless beside a stainless steel table. He had been electrocuted when he touched an ungrounded oscilloscope (an instrument that monitors the heart pacemaker) and the table at the same time.

In yet another hospital, a patient suddenly became rigid during a routine diagnostic procedure, warning personnel to cut the electric power of an instrument that was sending potentially lethal currents into his heart. Fortunately, the patient survived.

In a fourth hospital, an electrical switch broke and a patient was crushed to death by a descending X-ray machine.

And in a speech last November 16, Roger O. Egeberg, M.D., Assistant Secretary for Health and Scientific Affairs of the U.S. Department of Health, Education and Welfare, described another hospital tragedy: "Not long ago," Dr. Egeberg noted, "a woman in her midsixties entered a hospital in metropolitan Washington, D.C., for routine thyroid gland surgery. When the operation was completed and the patient was being sutured, the physician turned off the anesthesia machine. An explosion occurred, possibly caused by an electrical spark. Within four and a half hours the patient was dead as a result of the injuries she sustained in the blast."

Paradoxically, medical instruments that have brought hope of longer life to thousands of people have also increased a thousandfold the risks to hospital patients. "Life-saving" electrical devices used in hospitals across the country electrocute an average of three patients a day, at the lowest estimate. Other patients die as a result of electrical burns, explosions or loss of instrument control. Since the advent of the heart pacemaker and cardiac catheterization—the insertion of a catheter, or tube, into the heart—the hospital environment has become so dangerous that today it is the site of more electrical accidents than any industry except mining.

Spectacular advances in medical technology have unquestionably opened new horizons for people suffering from heart and lung disorders and other diseases. Those who may benefit —for example, the 20,000 patients who receive implanted heart pacemakers each year—may understandably be willing to hazard risks in hope of staying alive. But the myths of the medical machine lead us to believe that most of these risks are unavoidable. The tragedy is that most are not.

Most electrical accidents in hospitals occur because safety measures that can reduce risks are grossly neglected or even unknown among hospital staffs; because complex and highly dangerous equipment is installed in hospitals that have primitive wiring systems, and the equipment is operated by untrained personnel; and because machines that reach inside a human being and touch his heart are less well tested than plumbing devices in our bathrooms.

These accidents often occur because manufacturers design dangerous devices without making them fail-safe against even the most common mistakes of operators. The real risk for a hospital patient may be considerably less than esoteric. It may be the risk that hospital staff will decide to use a frayed electrical cord one more time, or, for the heart patient with an external pacemaker, that he will be placed in an electrically operated bed—a highly dangerous but common occurrence. Or instead of employing a qualified biomedical engineer, a hospital administrator may ask the building electrician to install complex new equipment.

Most of these instances of negligence remain hidden by the fact that physicians and hospitals habitually report deaths by electrocution as "cardiac arrest."

Electrical gadgetry and the accompanying hazards of electric shock are everywhere in our environment—in our homes, schools and offices. When a young guitarist is electrocuted by his instrument, or when a priest is killed by an electrically operated weight reducer—two incidents recently reported in the press—we want to know what went wrong. Was the guitar defective? Was the wiring bad? Did the victim use the machine improperly? Unfortunately, these questions are not often asked in hospitals, where at the very least 1,200 Americans are electrocuted annually during routine diagnostic and therapeutic procedures.

We do not even have a clear idea of the number of hospital fatalities caused by electric shock. Medical engineers such as Professor Hans von der Mosel, co-chairman of the Subcommittee on Electrical Safety of the Association for the Advancement of Medical Instrumentation and safety consultant to New York City's Health Services Administration, believe that the number might be 10 times as high as the conservative estimate of 1,200. Yet most of these deaths could have been prevented by adequate safety measures. (continued on page 176)

Photograph by Ben Swedowsky

RALPH NADER'S EXPOSE

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For the patient whose heart is made accessible to electric current through electrodes and catheters, merely touching the frame of a hospital bed, especially an electrically operated bed, may prove fatal. This happened to a 52-year-old man who was connected to an external pacemaker by means of a catheter inserted into the heart itself. Someone had attached to the pacemaker an ungrounded extension cord that eliminated the instrument's grounding system. When a current leaked from the pacemaker, as it frequently does, it passed through the catheter electrode into the patient's heart, then through the part of his body in contact with the grounded electrically elevated bed.

The death could have been prevented in at least three ways: if hospital staff had not attached an ungrounded extension cord to the pacemaker (extension cords should never be used with such equipment); if the patient had not been placed in an electrically operated bed; if the pacemaker had carried a device that limited the current in the patient's circuit to a safe level.

This death was investigated because it was the third such fatality in less than two months at that hospital. It is possible, even likely, that the other deaths, which were not investigated, were also due to electrocution. But most such deaths are not reported. Almost invariably, when electrocutions happen during diagnostic procedures in which the patient is hooked up to electronic systems, the deaths are listed as cardiac arrests. Without engineering analysis, it is difficult to tell whether a patient died of his disease or of a shock caused by the equipment. To protect themselves against malpractice suits, physicians and hospitals avoid such investigations, and many hazards go undetected and uncorrected. There have been few lawsuits over these deaths, and thus the hazards have been little publicized. Insurance companies that make studies of electrical hazards have not alerted the public to the dangers or to the incidence of death. Statistics have hidden the fact that a shock-hazard epidemic of critical proportions exists in our hospitals.

The hazards of electrical devices are not limited to delicate equipment such as the heart pacemaker. Routine electrical equipment may also cause death. Take the case of the patient who was squeezed to death when the switch controlling the X-ray machine's vertical movement failed while the machine was being lowered over him. He died before the technician could open the circuit breaker located some distance away.

What caused the switch to fail? A broken contact blade that shorted a circuit. The break had probably existed for some time. If the hospital had conducted regular equipment checks, the fault would probably have been discovered and corrected. In addition, precious time was lost because the main switch, which cuts all power to the instrument, was not easily accessible. Finally, the circuit breakers were not clearly marked, and the technician opened three different electrical circuits before he found the right one.

Nor are electrical accidents limited to patients. A young Canadian physician nearly died of electric shock when he pressed the discharge button on a defibrillator. This machine, used for correcting uncoordinated heartbeat, is inherently dangerous because it is designed to deliver a high-energy shock. Examination revealed that the ground wire in the three-prong plug had been broken, presumably when someone attempted to force the plug into a two-hole socket. Thus current was released—first into the chassis of the machine, then into the physician.

Inexcusable negligence

Some fatalities are caused by inexcusable negligence. Many devices are used with adapter plugs that don't ensure grounding. That is what happened with the hospital doctor who was found dead, the metallic switch of the oscilloscope in his right hand, his left hand touching a metal drawer of the stainless steel table on which the instrument was standing. A device in the power supply circuit of the oscilloscope had shorted, shooting 300 volts into the cabinet of the instrument. The oscilloscope should have been grounded through the grounding prong of the three-prong connector; instead a three-to-two-prong adapter (called a "cheater adapter") was in use. In this case, the adapter was completely unnecessary to connect the instrument, but the instrument was not designed to prevent the mistake. Because it was ungrounded, and because the doctor was touching a grounded steel table, the current passed through his right arm, through his trunk, heart and left arm into the grounded table.

Physicians and hospital personnel have been aware for some time of the hazards of electrically ignited explosions and external electric shock.

"What a crowd! I almost lost Junior!"

Some progress has been made in reducing the danger of explosions in operating rooms by employing standard safety precautions and, in a few hospitals, by eliminating flammable anesthetics. But there is little if any protection against a newer hazard—internal shock. Catheters, electrodes and probes have opened pathways to the heart through which very small accidental currents can kill a patient. A shock of 20 microamps across the heart can cause fibrillation, which after one minute results in irreversible brain damage and after three minutes, in death. At the surface of the body, a shock must be a thousand times greater to produce fibrillation.

Six Ways to Make Your Hospital Safer Electrically

1. Organize a citizens' group to investigate the administrator of your community hospital's electrical safety system. If possible, take an electrical engineer with you, or have one brief you on important questions to ask. Does the hospital have proper wiring? Does the hospital utilize the services of biomedical engineers? Are devices and device systems tested before they are hooked up to a patient? What are the provisions for testing new equipment?
2. Citizens and community groups can demand investigation of hospital fatalities. Find out who monitors accidents in your community hospital. When accidents are attributed to "cardiac arrest," was that the real cause of death? Are electrical systems always tested after deaths and injuries occur that could be attributed to electrical or equipment failure?
3. Is there an electrical device safety committee at your hospital? Organize a group of concerned citizens to meet with hospital review committees to ask what precautions are taken in the use of electrical devices.
4. Ask the company that insures your community hospital for statistics on electrical accidents at the hospital.
5. Urge your newspaper to make a thorough investigation of electrical devices in local hospitals and to publicize any particular problems.
6. If you are a professional engineer, take the lead in exposing and correcting electrical problems in local hospitals.

If properly grounded, most devices are safe when used by themselves. But most of the time, the patient is connected not to one but to several electrical devices. In addition, he may touch any number of other electric appliances—bed, radio, television, clock, lamp. He may also come in contact with routine equipment, such as portable X-ray machines, physiotherapy apparatus and respirators. In such an environment, the risk is extremely great that a stray electrical current will complete a circuit to ground through the patient. Most electrocutions happen in just this way. Prevention of death or injury from internal shock requires expert planning, sophisticated wiring systems, and careful, constant testing.

Few hospitals, even the newer ones, have adequate electric wiring systems. Most need extensive modernization to provide a safe environment for new electrical devices that are in widespread use. Electrical overloading is common. Many hospital outlets are incorrectly wired or provide no ground contact. In most cases these outlets were installed by hospital electricians when equipment appeared with three wires. As long as the plugs went in, the electrician believed his job was done.

Only three hospitals in the country have biomedical engineers on their staffs to supervise the operation and maintenance of complex machines: Downstate Medical Center in New York City; Sinai Hospital in Baltimore; and Charles S. Wilson Hospital in Johnson City, N.Y. Most hospitals simply turn over the apparatus to a staff physician who may have worked with electronic equipment. Hospitals do not yet have electrical device safety committees comparable to drug safety committees, although the two hazards are equally great. Few physicians who deal with these devices know as much about the concepts behind them or about their use as they know about pharmacology. Yet for years physicians operated these devices without recognizing either their potential hazards or the actual fatalities they caused. Countless deaths attributed to cardiac arrest are now believed to have been caused by internal electric *(continued)*

shock. Even now that there is greater understanding of the risks posed by the new hospital environment, precautionary measures are inadequate.

While inadequate hospital facilities and errors in using the machines are leading causes of accidents, mechanical defects also play a part in imperiling patients' lives. One medical engineer, Seymour Ben-Zvi, tested several thousand instruments at Downstate Medical Center in New York City. He reported that 40 percent were defective. Every one of the 10 defibrillators he tested contained defects. One was capable of discharging high voltage into a patient before the physician signaled for it. Such a defect could kill both patient and physician. Another instrument had what the manufacturer thought was an insulator; it was actually a good conductor of electricity —a potentially fatal flaw that should have been discovered through testing. (The testing program at Downstate began in 1956, and Ben-Zvi states that most manufacturers now agree to correct defects found.)

C. W. Walter, a clinical professor of surgery at Harvard Medical School, has reported that two prominent firms are now selling highly dangerous machines. Poor circuit design is a common criticism, and many devices have problems stemming from high leakage of current, problems often revealed only through the death of a patient. Some manufacturers offer to replace equipment; they cannot replace a dead person.

Toilets and pacemakers

Mrs. Virginia Knauer, President Nixon's Assistant for Consumer Affairs, has pointed out that toilet valves must pass several preclearance tests before they are installed in our bathrooms, but a pacemaker that is inserted into our hearts need not be tested at all. Heart pacemakers, artificial kidneys, hip pins and respirators—none are subject to standard inspection or regulation—as are drugs, for example.

Manufacturing of medical devices is a $500-million-a-year industry engaged in by more than 1,000 firms. Without regulations or standards, there has been little impetus for these firms to standardize their products. Manufacturers' resistance to standardization has created an unnecessary hazard, since each hospital must sort out discrepancies in connectors and devise a system to prevent hazardous currents from being applied to helpless patients. Generally, the manufacturer considers his product a separate unit rather than part of a total treatment system, although a device is rarely used by itself.

In designing instruments, manufacturers almost totally ignore the ease with which mistakes can be made in the hospital environment, where personnel are often hurried, strained or tired, and untrained in the use of the equipment. Fatal errors are made that could be prevented by safer design.

Often the grounding devices furnished with electrical equipment are weak, easily broken and not designed for rough handling. They are not remotely foolproof, not fail-safe and not even reliable. Cords and plugs, the most vulnerable part of the electrical safety system, are usually "totally inadequate," according to Professor Walter. On occasion, a complex and expensive piece of equipment is equipped with a cheap, inefficient plug.

Fatally for patients and staff, manufacturers often assume that users have technical competence, which they almost universally lack. Instruction booklets, labels, foolproofing and protection devices are far inferior to what is needed.

One respected independent testing agency that has begun to test and evaluate medical equipment reports an "appalling" number of defective instruments. Research at the Emergency Care Research Institute of Philadelphia revealed, for example, defective respirators that were "totally unable to support respiration." The Food and Drug Administration has recalled a number of these devices.

Dr. Joel J. Nobel, ECRI's director of research, says that "the number of life-threatening defects is truly appalling. Most are basic design deficiencies."

ECRI is a nonprofit organization supported by government agencies, hospitals and private contributions. No staff member receives consulting fees from the health devices industry. ECRI findings indicate that, in the absence of objective testing and evaluation, unsafe equipment is being used in hospitals that are unequipped to pretest it.

Hospital associations in three regions —California, Texas and New England —are in the process of setting up medical product information exchange systems. Central testing programs to serve all hospitals in a region are much more feasible than tests conducted in individual hospitals, but such programs have yet to get underway.

At present, there are no government regulations requiring premarket clearance or standards to ensure the safety and performance of certain medical devices, such as catheters, pacemakers, diathermy machines and bone pins. During the past several years, efforts to bring new devices under regulations have failed. Presidents Kennedy, Johnson and Nixon have supported regulations and minimum standards for medical devices. In September 1970 a study group appointed by President Nixon and headed by Dr. Theodore Cooper, Director of the National Heart and Lung Institute of the National Institutes of Health, recommended legislation to regulate these devices.

A bill has been introduced by Congressman Thomas Foley (D., Wash.) to establish regulations and standards for devices not covered by present law. This bill was originally proposed in 1969, but no action has yet been taken. Legislation has been stymied in part by claims that standards for such instruments are difficult to set. But the failure of physicians to publicize the real extent of the hazards is the reason why the need for legislation has been unnoticed.

Pretesting of these devices by independent testing agencies and establishment of uniform government standards will help ensure that the instruments are safe, that they are fail-safe and that they assume much less knowledge and expertise on the part of the typical hospital employee who runs them.

But beyond government standards, what is needed is greater vigilance by hospitals and physicians. In the absence of trained personnel, adequate electrical systems and rigid inspection and testing, even the best designed machine may become a killer. Unfortunately, there is little indication, on a broad scale, that hospitals and physicians are prepared to make a major commitment to electrical safety. Instead, there is every indication that accidents are occurring more frequently. The public may well ask where the electric safety committees in hospitals are, or the services of biomedical engineers. Where are the research grants to study questions of safety? Where is the leadership of medical organizations that should be demanding safety from manufacturers and help in ensuring safety from governments? I do not believe the public should have to accept the response one physician made to the problem of hospital safety: that after all, most electrical accidents occur in the home.

It is true that there is too little understanding of electrical hazards. The use of two-prong plugs (without a third grounding wire) is a simple hazard that

continues to exist in many homes and other buildings. The naïveté of physicians who use intricate devices is undoubtedly shared by many other people who do not understand when or why electrical devices can be hazardous. The housewife who simultaneously touches a toaster and a refrigerator handle and receives a shock usually lives to return the toaster, or change the wiring, or complain to the manufacturer. The heart patient who receives the same kind of shock is not so fortunate.

If we have the technology to stimulate the heart, to sustain life and to probe the innermost regions of the body, we also have the means to make devices that are safe from human error. The unprecedented hope offered by new medical technology does not need to be accompanied by unprecedented risk. Such avoidable tragedies in our hospitals will not be stopped until manufacturers recognize the limitations of the personnel who use their devices, and until users demand that safety be built into the devices. Dangers that have been veiled as unavoidable risks, or risks inherent in the condition of the patient, must be exposed. Until they are, new medical devices will continue their Jekyll-and-Hyde role—they are life-giving devices for some, but death machines for others. **END**

A KITCHEN THAT WORKS

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13. Waste disposal. For food waste, disposers in sinks were highly favored. Trash, according to conversations with many women, continues to be a problem. Some said a large wastebasket was the answer, but where to put it in the kitchen remains a problem. Pull-out containers or drawers with liners were attractive, but not always easily accessible. Trash compactors interested the women questioned, but were still relatively unknown.

14. Kitchen storage space. Storage space—or the lack of it—brought the most complaints of all from the women surveyed. Everyone wanted more storage space. Some 89% said the kitchen needs extra storage away from the main work area for utensils and for food and supplies bought in bulk. The majority (54%) wanted a walk-in pantry for extra storage. Some 35% said floor-to-ceiling cabinets with lots of shelves would do the trick. Another useful feature: special, easy-to-get-at space for the collection of today's plug-ins: frying pans, blenders, broilers, juicers, etc. Almost everyone wanted more counterspace—some 47% thought it would be useful to vary some counter heights from the standard 36".

15. Floors. Vinyl floors were favored by the majority, with carpeting running second. Ceramic, brick and wood floors all got minority approval. In talks with women we learned that they especially liked vinyl floors because they are easy to clean and versatile in style. Sometimes, women liked several different materials in the same kitchen —vinyl in the work area and carpeting in the eating area, for example.

16. Cabinets. Three out of four women selected wood cabinets. About a third preferred the new plastic-fronted cabinets. Few wanted metal cabinets and a majority liked the look of wood graining whether real or synthetic. As for style, 50% preferred a plain façade. About one-third liked the more decorative cabinets. Interestingly, despite an apparent preference for plain cabinets, they are the least available in good quality construction. In general women said cabinet design, including storage arrangements, still has room for improvement. Many bemoaned the fact that special space-saving features —sliding shelves and bins, for example —were often so costly that they could not be included in the kitchen plan.

17. Wall finishes. Most women liked painted walls. Paper and coated fabric tied as second choices. There was considerable variation in preferences according to the part of the country and the style of the home.

18. Counters. Nine out of ten women preferred plastic counter tops. Other popular alternatives: wood and tile. A number saw the advantage of having more than one kind of a surface in the kitchen, wood sections perhaps for slicing and heat-proof sections near the range cooking top.

19. Other features: Although not part of the survey, two other important features of kitchen design were repeatedly stressed in our talks with women: Good natural light by day and well-designed artificial lighting by night. Also important: an effective ventilation system that whisks away cooking odors and heat. **END**