Clinical Engineering

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Complications of and improvements in pneumatic tourniquets used in surgery

In North America, it is estimated that at least 10,000 pneumatic tourniquets are used in more than 1 million surgical procedures annually. The increasingly widespread use of pneumatic tourniquets in surgery of the extremities has been accompanied by continuing reports of injuries. Interest in tourniquet-induced complications has recently increased because of concern about potential legal liability. Results are presented from the investigation of 15 cases of complications suspected of being associated with the use of pneumatic tourniquets over an 18-month period. Factors leading to tourniquet-induced complications are identified, difficulties preventing an accurate estimate of the true incidence of such complications are reviewed, and the key elements of a program of inspections aimed at periodically assessing the safety and performance of pneumatic tourniquets are outlined. To reduce the hazards associated with the use of pneumatic tourniquets, a new microprocessor-based tourniquet is being developed. Initial results on a series of 30 patients indicate that the new microprocessor-based tourniquet—in addition to being significantly safer, more accurate, and more reliable—will considerably reduce operating costs by reducing the labor-intensiveness currently associated with tourniquet usage.

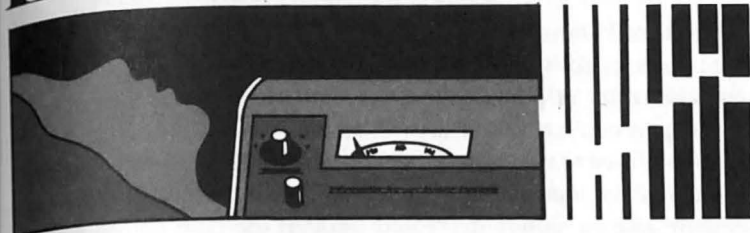*medical device hazards; pneumatic tourniquets; surgical tourniquets; tourniquet-induced complications; tourniquets*

THE pneumatic tourniquet, unless specifically contraindicated, is now almost universally used in surgery on the extremities: The dry field produced by the pneumatic tourniquet makes dissection easier and surgical techniques less traumatic, as well as decreases the time required for operations. In North America, it is estimated that at least 10,000 pneumatic tourniquets are used in more than 1 million surgical procedures annually.

The history of nonpneumatic and pneumatic tourniquets in surgery has been extensively reviewed elsewhere (Klenerman 1962). A tourniquet was first employed in surgical procedures other than amputations in 1864. Since that time, two technical advances facilitated the development of bloodless-field surgery: the introduction by Johann Esmarch (1823–1908) of an elastic-wrap bandage for exsanguination of a limb prior to the application of a tourniquet, and the introduction of a pneumatic tourniquet by Harvey Cushing in 1904 (Cushing 1904).

Factors leading to tourniquet-induced complications will be identified, difficulties preventing an accurate estimate of the true evidence of such complications will be reviewed, and the key elements of an inspection program aimed at periodically assessing the safety and performance of pneumatic tourniquets will be outlined. In addition, a new microprocessor-based tourniquet, designed to reduce the hazards currently associated with the use of pneumatic tourniquets, will be described.

Complications from Pneumatic Tourniquets

The widespread use of tourniquets in surgery has been accompanied by continuing reports of limb paralysis, nerve damage, and other injuries (Moldaver 1954; Sanders 1973; *CMAJ* 1973; Arenson and Weil 1976; Flewellen and Jarem 1978; Health Protection Branch 1978; Weingarden et al. 1979; Rorabeck and Kennedy 1980). These complications may result from four factors: (a) excessive pressure causing nerve compression at the cuff site (Spiegel and Lewin 1945; Lundborg 1970; Middleton and Varian 1974: Rudge 1974; Trojaborg 1977), (b) insufficient pressure causing passive congestion or hemorrhagic infiltration of the nerve (Arenson and Weil), (c) a lengthy period of tourniquet application (Bruner 1970; Flatt 1972; Bolton and McFarlane 1978; Weingarden et al.), or (d) application without consideration of the local anatomy (Sanders).

Many reported cases of preventable nerve damage, limb paralysis, and other injuries have resulted from these four factors, the most common of which is overpressurization (Wheeler and Lipscomb 1964; Hamilton and Sokoll 1967; Prevoznik 1970; Bruner; Fry 1972; Flatt; Burchell and Stack 1973). Unfortunately, the true incidence of tourniquet-induced complications cannot be estimated accurately: The "tourniquet paralysis syndrome" (Moldaver) may be difficult to detect or masked by the effects of surgery because the damage is often transient and reversible to a large extent and because such incidents may not be consistently reported due to concern about potential legal liability. For example, a hospital was recently found liable for a patient's nerve injury incurred as a result of excessive pressure applied to her arm by a tourniquet (*Citation* 1978).

At the Vancouver General Hospital and nearby institutions, 15 incidents of suspected tourniquet-induced complications were investigated in an 18-month period. During this time, pneumatic tourniquets were used in approximately 10,000 procedures. Thus the apparent incidence is 0.15%, although this estimate is not considered reliable for the reasons indicated earlier. Six of the reported incidents involved possible nerve injuries or paralysis in the upper limb associated with overpressurization; two of these cases resulted in a significant degree of paralysis and loss of sensation, which gradually improved during the

6-month period after surgery. Four of the tourniquets involved in these incidents were found to have malfunctioning pressure-regulating mechanisms or inherent hysteresis in the pressure-regulating mechanisms, which permitted the actual pressure to rise 150–400 mmHg above the desired pressure. The other two tourniquets involved in these incidents were found to have aneroid pressure gauges that were inaccurately calibrated by approximately 200 mmHg. Seven other incidents involved soft-tissue injuries, such as blistering, reddening, bruising, and pinching of the skin at the cuff site; these injuries were attributed to chemical burns from prep solutions, shearing forces generated by inflation of the cuff, marginal overpressurization, inadequate cuff compliance, or inadequate preparation of the cuff site. Another two incidents involved passive congestion of the surgical site as a result of sudden depressurization caused by gas depletion and cuff disconnection. It should perhaps be noted that the nature, extent, and frequency of the reported incidents may have been affected by the increased awareness of the problem after the investigation of the first serious incident and by the resultant greatly increased effort directed at the inspection, monitoring, and controlling of the function of pneumatic tourniquets.

Characteristics of Pneumatic Tourniquets

To minimize hazards associated with the use of pneumatic tourniquets, maximum periods of application and maximum safe pressures have been proposed on an empirical basis. (Bruner; Smith 1971; Flatt). Furthermore, the possibility of redesigning the cuff to reduce the risk of injury has been suggested (Griffiths and Heywood 1973; Burchell and Stack). It has also been proposed that cuff pressure should be minimized by making it a function of the patient's preoperative systolic pressure (Sanders 1973; Klenerman and Hulands 1979). Attempts have been made to reduce injuries caused by overpressurization by incorporating better safety features into pneumatic tourniquets: For example, rocker valves of the type used in pressure cookers have been employed as pressure-release valves (Wheeler and Lipscomb; Hamilton and Sokoll 1967). However, limitations inherent in the technology of the current generation of pneumatic tourniquets seem to preclude the practical implementation of significant safety improvements. Fig. 1, for example, shows a typical control cycle for the Kidde model 400 Pneumatic Tourniquet (Walter Kidde Inc., Belleville NJ), which can have a hysteresis of 150 mmHg in its single-stage pressure-regulating mechanism (Health Protection Branch; Johnson et al. 1980).

In view of the possibility of such large pressure variations under normal conditions, it has been proposed that the gauges indicating cuff pressure in pneumatic tourniquets should be constantly monitored to ensure safe operation (Health Protection Branch). The calibration of the aneroid pressure gauges should be checked frequently: Calibration checks at daily intervals, or prior to each procedure, have been recommended (Bruner; Prevoznik; Flatt). Finally, pneumatic tourniquets should be frequently serviced and regularly subjected to performance-assurance tests. Full implementation of the above recommendations could be labor-intensive; in practice, however, it is estimated that a combination of daily calibration checks, a more rigorous set of performance-assurance tests at monthly intervals, and adequate controlling and monitoring of tourniquet function at 5-min intervals during surgery would occupy only 10–15% of an operating-room nurse's or technician's time.

Inspection of Tourniquets

Rigorous inspections of twelve pneumatic tourniquets at quarterly intervals were initiated at Vancouver General Hospital in 1979. Each inspection includes determinations of whether the actual pressure is accurate to within 5% of the set pressure, whether the hysteresis

exceeds 200 mmHg, and whether the actual pressure remains stable to within 10% of the set pressure over a 15-min period.

The accuracy test is conducted by comparing the pressures indicated on a test gauge at set pressures in the tourniquet of 0, 100, 300, and 600 mmHg, in increasing and then decreasing order. The effect, if any, of tapping on the aneroid gauge at each pressure is noted, and any effect greater than 15 mmHg is considered to be unacceptable. The hysteresis test is conducted by first connecting a rubber bulb from a sphygmomanometer set in parallel with the cuff of the tourniquet and then inflating the cuff monotonically from 0 to 300 mmHg. At that pressure, the bulb is used to incrementally increase the pressure until a plateau is reached on the tourniquet gauge and the plateau pressure is recorded; pressure is then slowly decreased through the bulb until a constant pressure value is reached, and thus recorded. The difference represents one hysteresis value. A second hysteresis value is obtained by repeating the previously described procedure after first approaching a pressure of 300 mmHg from a higher pressure of 500 mmHg. The stability test is performed by first setting the tourniquet at a pressure of 550 mmHg from a pressure at least 200 mmHg higher, occluding the hose at the cuff with a hemostat, and then observing the indicated pressure after 15 min: The pressure should not have increased noticeably, and should not have decreased by more than 10%. The physical condition of the
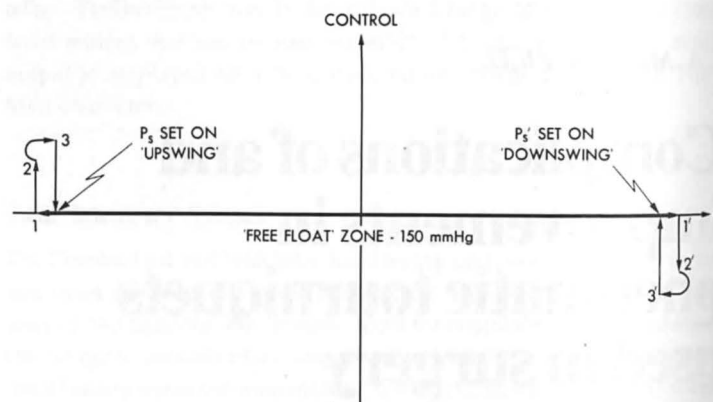

Fig. 1. Typical control cycle for a pneumatic tourniquet. If the pressure is set at P_s on the "upswing," a leak in the regulating valve may cause the pressure to rise by 150 mmHg before the regulator acts (in sequence 1′, 2′, 3′) to stabilize the pressure near P'_s. Conversely, setting the pressure at P'_s on the "downswing" with a leak in the cuff would lead to the pressure stabilizing 150 mmHg lower at P_s.
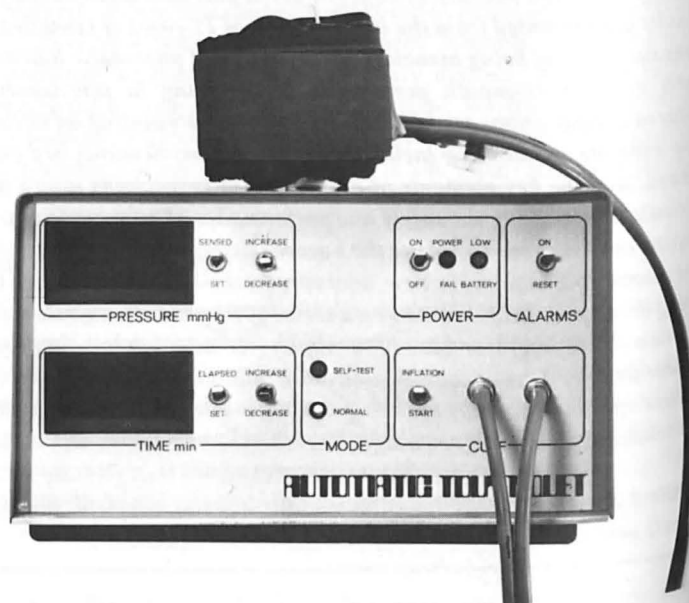

Fig. 2. Front panel of microprocessor-based tourniquet.

niquet—including the aneroid gauge, cuff, tubing, connectors, valves, and pressure-regulating mechanism—is also examined during each inspection to determine if any components may have been damaged or dropped.

In the 33 inspections of pneumatic tourniquets conducted to date, there have been 8 failures of the accuracy test, 15 failures of the hysteresis test, and 3 failures of the stability test. A number of other, less serious problems have also been identified as a result of the inspections. In view of these results, it is suggested that other hospitals consider similar inspection programs for pneumatic tourniquets.

The results of the inspections indicate that these pneumatic tourniquets have the following undesirable characteristics: a mechanical pressure-regulating valve that is prone to malfunction; a pressure-regulation mechanism that has sufficient hysteresis to make it hazardous during normal operation; a reservoir of compressed Freon gas that is capable of generating a pressure of more than twice the maximum safe level; an aneroid gauge that deteriorates with use and provides inherently inaccurate indications of cuff pressure; a lack of audio or visual alarms to alert the staff in the event of overpressurization, underpressurization, or other hazardous conditions such as excessive periods of application; and the lack of a fail-safe mechanism to limit the maximum pressure in the cuff to a safe level. Despite these clearly undesirable characteristics, the pneumatic tourniquets used at Vancouver General, and other types of pneumatic tourniquets with similar characteristics, are widely used throughout North America. Modification of such devices in an attempt to achieve a desirable level of safety, accuracy, and reliability, with a minimal degree of labor-intensiveness, does not seem feasible.

Microprocessor-Based Tourniquet

As part of an effort to significantly reduce the nature and extent of the hazards associated with the use of tourniquets in surgery, a microprocessor-based tourniquet has been developed. An outline of the structure and function of this device has been presented elsewhere (McEwen and McGraw 1979; McEwen et al. 1980; McGraw et al., in press). The front panel of the microprocessor-based tourniquet can be seen in Fig. 2; a block diagram of the device is shown in Fig. 3. The device is based on an 8-bit microprocessor (model 8085A, Intel Corp., Santa Clara CA) with a 512-byte random-access memory and a 2K-byte programmable read-only memory. Cuff pressure is controlled by means of the pressure-generating element and an electrical pressure-release valve shown in Fig. 3. The pressure-generating element in the prototype is a solenoid/diaphragm pump, with appropriate control circuitry and modifications to limit the maximum pressure to 500 mmHg. Data obtained from the pressure transducer/processor depicted in Fig. 3 are used in regulating cuff pressure to within ±6 mmHg. The performance of the microprocessor-based tourniquet is illustrated in Fig. 4, which shows that the pressure regulation achieved by the device is an order of magnitude better than that of commonly used pneumatic tourniquets. As indicated in Fig. 2, the microprocessor-based tourniquet has been designed for use with a cuff having two separate lines for incoming and outgoing air, to protect against an undetected malfunction caused by kinking and occlusion of the tubing; however, to date, conventional one-line cuffs and adapters have been used.

When the power switch of the microprocessor-based tourniquet is first turned on, a self-test mode is automatically entered, permitting rapid verification of the integrity of displays and audio/visual alarms. Initially depressing an "alarm reset" switch changes the state of the device to a normal mode and resets the alarms. A desired pressure can then be set by gradually increasing or decreasing between 0 and 500 mmHg from a preselected nominal level of 200 mmHg. Similarly, the intended period of inflation of the cuff can be set by gradually increasing or decreasing between 0 and 180 min from a preselected nominal time of 60 min. To set either the pressure or the time (see Fig. 2), two switches must be activated simultaneously to minimize the probability of inadvertent changes.

To initially inflate the cuff, an "inflation start" switch is depressed. When the pressure in the cuff reaches the set level, an elapsed-time clock starts. In their normal positions, the controls are designed to enable the light-emitting diode displays to indicate instantaneous values—i.e., the pressure sensed in the cuff line (in millimeters of mercury) and the elapsed time (in minutes). To display and check the set value of pressure or time, the operator can momentarily depress the appropriate switch to the "set" position. If the sensed pressure differs from the set of pressure by more than ±15 mmHg, or if the specified elapsed time is exceeded, or if there is a failure in the alternating current power, appropriate audio/visual alarms will activate to permit rapid identification of the problem. Although battery backup is provided in the prototype to maintain the memory, sensing, display, and alarm functions for up to 1 hour, the battery is not designed to operate the pressure-control elements. In the event of any alarm condition, the operator can suppress the audio indicator for 30 sec by depressing the "alarm reset" switch, but both audio and visual alarms can only be
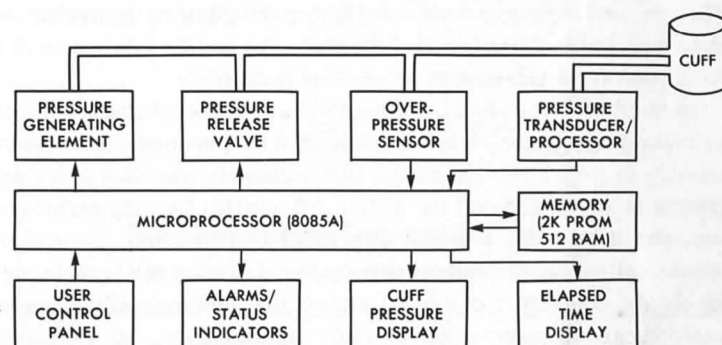

Fig. 3. Block diagram of microprocessor-based tourniquet.
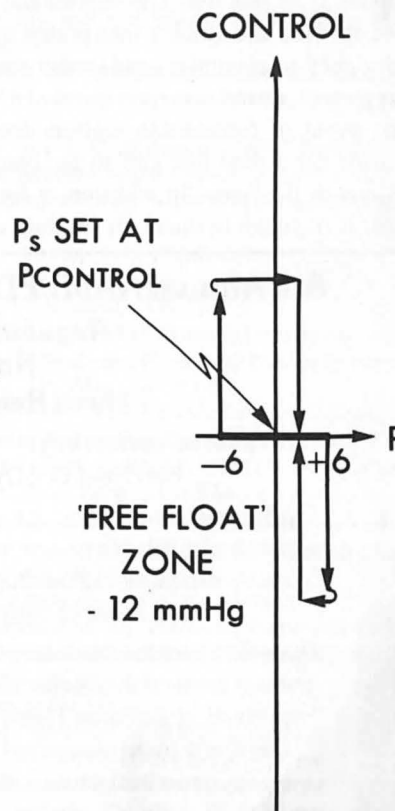

Fig. 4. Typical control cycle for the microprocessor-based tourniquet. The performance of the microprocessor-based tourniquet in regulating pressure about P_s is an order of magnitude better than that of the pneumatic tourniquet.

reset permanently after the underlying problem has been corrected. To deflate the tourniquet at the end of the procedure, the desired pressure is set to zero.

A technical evaluation of the prototype to ensure compliance with pertinent standards resulted in some design changes. The prototype was then employed in a series of 30 surgical procedures, chosen as representative of the range of procedures in which pneumatic tourniquets are currently used. Patients exhibiting unusual or complicated motor or sensory defects were excluded from the trials. Perioperative patient evaluation included in the trials consisted of presurgical and postsurgical examinations by an orthopedic resident employing a written protocol and structured questionnaire to obtain pertinent data concerning the patient's history and physical condition, the status of the affected limb, and any sensory or motor deficits. Details concerning the protocol and the results of the examinations have been reported elsewhere (McGraw et al.). Briefly, no significant injuries or defects that might be attributed to the use of the tourniquet were discovered. In addition, in each of the 30 cases in which the tourniquet was used, a biomedical engineer or technician monitored the function of the device and gathered information on a structured questionnaire concerning how the device was used and accepted by the clinical staff. The comments, criticisms, and suggestions obtained during this phase of the evaluation were employed in the redesign of the prototype and the fabrication of a second unit for a subsequent series of clinical trials.

The microprocessor-based tourniquet has a number of characteristics that make it significantly less hazardous than the pneumatic tourniquets currently in use. First, the device can accurately maintain a desired pressure in an inflated cuff (to within ± 6 mmHg) for long periods of time, and it provides a digital display of cuff pressure. Second, it automatically monitors and provides a digital display of elapsed time. The device contains audio/visual alarms that automatically warn of hazardous overpressurization or underpressurization, an excessive period of inflation, or failure of a.c. power. Other characteristics increase the probability of safe use: The control and display panel was designed to be easily used and quickly interpreted by clinical staff; the controls were designed to minimize inadvertent resetting; the device was designed to protect against overpressurization or sudden depressurization in the event of foreseeable malfunctions or misuse; and provision was made for a dual-line cuff to facilitate the detection of kinks or occlusions in the lines. In addition, a backup battery with automatic charger is included to maintain sensing, display, and alarm functions during an interruption of a.c. power, and a self-test mode that is entered initially helps ensure integrity of displays and alarms prior to use.

The ability to accurately control pressure in the cuff with a microprocessor-based tourniquet may permit the use of much lower, less hazardous pressures than are widely used at present. In the second phase of clinical trials of the microprocessor-based tourniquet, for example, cuff pressure is routinely being set at 325 mmHg for the lower limbs of normal adults, and 225 mmHg for the upper limbs of normal adults. This represents as much as 50% reduction in inflation pressure, when compared with the maximum pressures widely advocated and employed with pneumatic tourniquets at present (Boyd 1971; Flewellen and Jarem). The use of lower, inherently less hazardous pressures has been advocated previously. For example, it has been suggested that cuff pressures could normally be set at 70 mmHg above the patient's preoperative systolic pressure (Sanders), and that the cuff pressures could be set at twice the maximum systolic pressure for surgery of the lower limbs, provided the patient was normotensive and did not have grossly hypertrophied or obese thighs (Klenerman and Hulands). However, the previously described limitations in the accuracy and reliability of the current generation of pneumatic tourniquets could make implementation of suggestions regarding lower pressures hazardous or excessively labor-intensive, or both. In contrast, the lower pressures mentioned above are being used in conjunction with the microprocessor-based tourniquet, with no apparent increase in risk or labor-intensiveness. The results of a preliminary study indicate that in the future it might even be feasible to incorporate an automatic sphygmomanometer into a microprocessor-based tourniquet that could, in conjunction with a dual cuff, noninvasively monitor a patient's intraoperative systolic pressure and dynamically maintain the minimal pressure necessary for a bloodless field.

The results of the trials conducted to date indicate that the microprocessor-based tourniquet can significantly reduce the labor-intensiveness associated with tourniquet usage. It requires little attention, except in the event of an alarm condition. It is estimated that the use of the device could result in the reduction of 0.1 full-time-equivalent staff, with a significantly less hazardous quality of care. On the basis of this estimate, together with comparisons of order-of-magnitude estimates concerning the costs of compressed gas, electrical power, repairs, and production costs, it is estimated that the use of a microprocessor-based tourniquet would pay for itself within 1 year.

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Thus, a significant improvement in the quality of care could be achieved simultaneously with a net reduction in the overall costs associated with tourniquet usage.

Summary

Routine usage of a microprocessor-based tourniquet such as the one that has been developed should lead to a significant reduction in the nature and extent of the hazards currently associated with the use of pneumatic tourniquets in surgery. It should also facilitate further advances, such as improvements in cuff design and the development of more sophisticated devices and even better performance. Moreover, this increase in safety and reduction of potential legal liability should be achieved with a net reduction in costs through a reduction in supply costs and in the labor-intensiveness currently associated with tourniquet usage.

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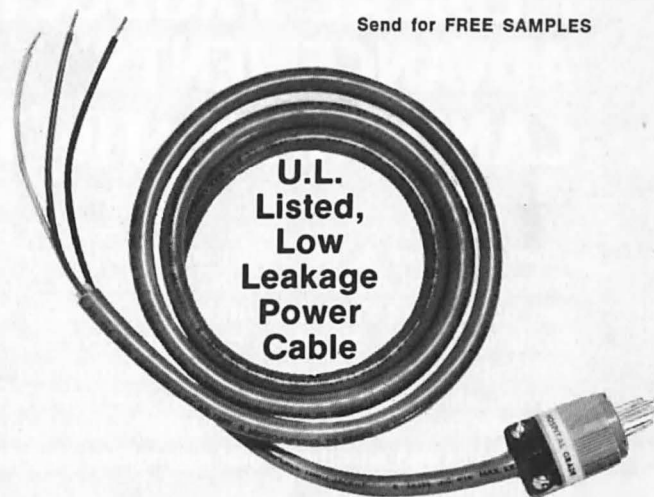
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