VETERANS ADMINISTRATION PROSTHETICS CENTER RESEARCH REPORT

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Following is a report of progress made during the 6-month period of July 1, 1975, to December 31, 1975, on various research, development, and evaluation projects performed by the VA Prosthetics Center. Included are reviews of the basic concepts that guide the VAPC in its day-to-day activities. Max Nacht, Technical Writer, VAPC, provided the editorial and technical writing support for this effort.

Hundreds of devices for the handicapped, that have been described in our Research Reports since we began publishing these reports more than 12 years ago, have been procured, tested, and redeployed during that time. Without the dedication, diligence, expertise, and forbearance of the VA Supply Service, these programs could not have been carried out. We therefore now wish to express our heartfelt thanks, belatedly but nonetheless sincerely, to Messrs. Joseph Landi, Jr., Robert Riggans, Reuben Chambers, Peter Odiot, John J. Burns, and Bernard Cutler, and to all their colleagues in Supply Service.

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I. DEVELOPMENT AND EVALUATION

A. Prosthetics

1. *Lower Limb*

a. *Graphite-Epoxy Composite Shank for Partial Thigh Endoskeletal Prostheses.* This is the second in a series of reports beginning in the Spring 1975 Bulletin (BPR 10-23), pages 220 and 221.

The two composite shanks described in the earlier Bulletin have been fitted on two patients. Both patients were fitted with hydraulic knees, one with a Mauch SNS, the other with a Dupaco unit. Both patients are young, quite active, and very demanding of their prostheses. Their reactions in the first few months of wear have been favorable, and no material failures have occurred. We anticipate the eventual commercial production of this device.

b. *Polypropylene Hip Joint and Pelvic Band.* Suction is the primary means of suspension used in above-knee prostheses. For various reasons, however, as in the case of a short stump, a flabby stump, or the presence of scar tissue, it is often necessary to use another means of suspension. The suspension system generally used in these cases is a pelvic belt with

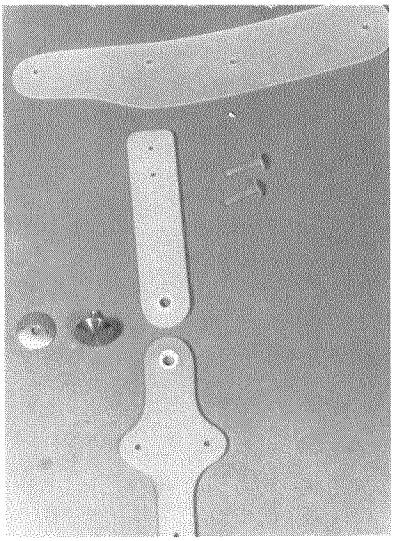

FIGURE 1. — Components of polypropylene pelvic joint.

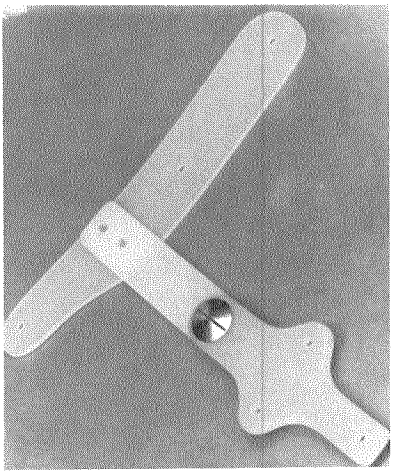

FIGURE 2. — Assembled polypropylene pelvic joint.

a pelvic band and hip joint. Generally, the pelvic band is made of aluminum and the jip joint is heavy steel.

A few years ago, the VA Prosthetics Center developed a spring-steel pelvic joint that was light in weight and more flexible than previous types of pelvic joints. It provided greater freedom of motion for the amputee. And except for a clicking sound that seemed to develop in the joint bore after a few months of wear, this joint was quite successful.

Recently, the successful uses of plastic joints in the field of orthotics have encouraged us to develop a polypropylene pelvic joint and band. We believe it has several advantages over the steel joint. These advantages are:

1. The polypropylene joint is one-fourth the weight (approximately 110 g).
2. The greater flexibility of polypropylene should make fitting easier and allow the patient more freedom of motion.
3. If produced in volume, a polypropylene joint will be considerably less expensive.

The polypropylene pelvic joint is similar in design to the steel joint and therefore presents no production problems. Nyliners are used in the joint bore and, at the present time, the joint screw is stainless steel. Plastic rivets are used to fasten the band to the joint (Fig. 1 and 2).

2. *Upper Limb*

Salt-Water-Resistant Below-Elbow Prostheses. Because conventional prostheses tend to corrode in salt water, and give off reflections that might attract sharks, a request for development of a below-elbow prosthesis for skindiving was acted upon by the VA Prosthetics Center. At first we attempted to coat all metal components of a conventional prosthesis with nylon. This proved to be an unworkable solution because we were unable to control the thickness of the coating in areas requiring close tolerances.

Our next attempt was to chemically adhere a dull, hard coating for aluminum to a conventional prosthesis of aluminum construction. This attempt proved successful; this time we were able to control the thickness of the coating.

We then modified a Dorrance hook (Fig. 3) by adding a stainless steel spring, thereby providing the equivalent of the Sierra hook worn by the patient and which he was accustomed to. Perlon was used to replace the stainless steel cable of the conventional prosthesis, and Pelite and canvas were used in place of the conventional leather (Fig. 4).

The patient will now perform his own evaluation of the device to see if it meets his requirements.

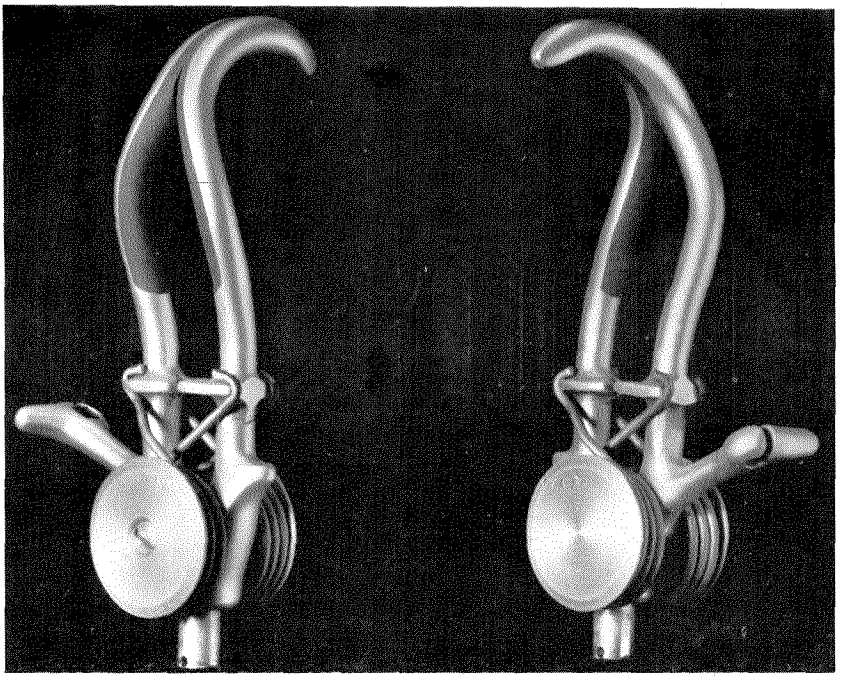

FIGURE 3. — Modified Dorrance hook.

B. Orthotics

1. *Lower Limb*

Polypropylene Knee Orthosis. This is the second in a series of reports beginning in the Spring 1975 Bulletin (BPR 10-23), page 225.

Good results in fitting the Polypropylene Knee Orthosis to patients have continued. Acceptance of the device by patients has been excellent and no major fitting or material problems have developed. It was therefore decided to have the polypropylene knee joints fabricated commercially. This should allow us to increase our patient workload and make the fitting process routine.

A considerable amount of interest in this orthosis has been shown by others in related facilities. This should be translated into fittings when commercially fabricated knee joints are available.

2. *Upper Limb*

Functional Elbow Orthosis. A majority of the functional upper-limb orthoses now available are designed for quadriplegics in wheelchairs. These bulky components are not suited for ambulatory patients with brachial plexus injuries or neurological disorders, who have lost upper-limb

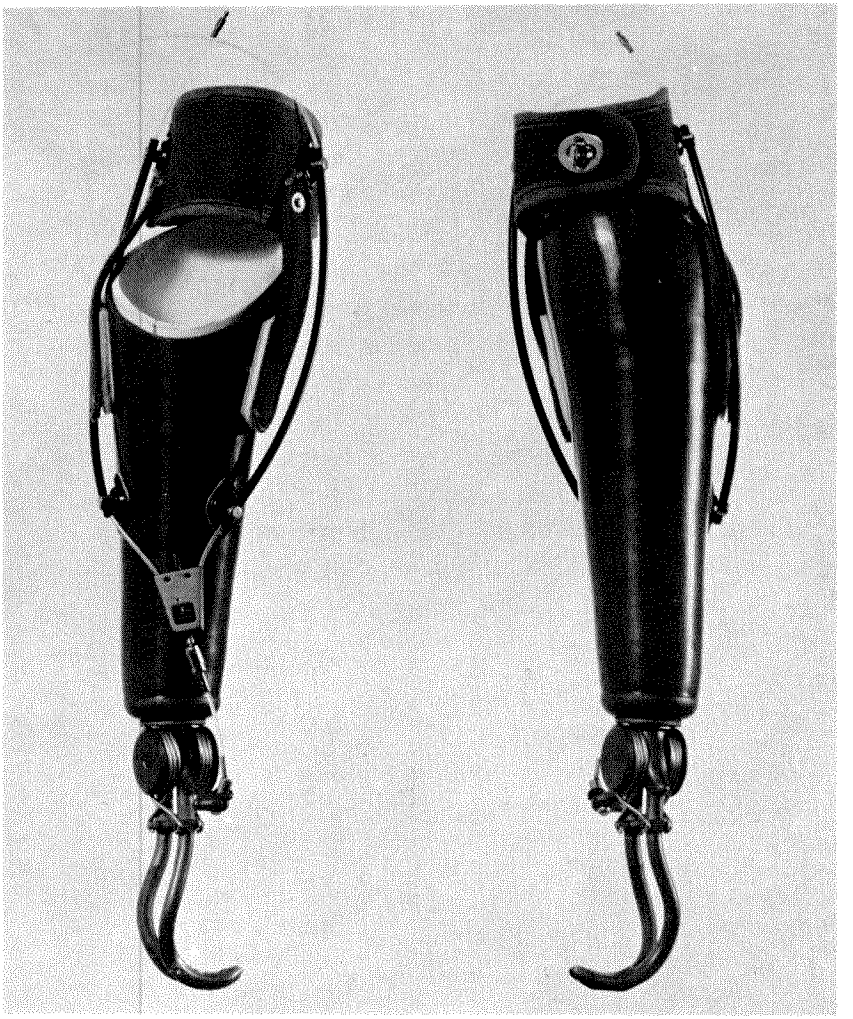

FIGURE 4. — Modified conventional below-elbow prosthesis.

muscle power. And the usual method of fitting ambulatory patients is with a prosthetic harness, which is only successful on patients with powerful shoulder muscles (Fig. 5).

At present we are experimenting with a pneumatic unit to assist elbow flexion (Fig. 6). This orthosis consists of a five-bar polycentric elbow linkage, with the force of gravity and the force required to flex the elbow counterbalanced by the stored energy in the pneumatic spring. The system is designed so that only minimal force is required to initiate elbow flexion. As flexion increases, force increases nonlinearly. Thus the force needed to extend the system is greater than the force needed for flexion.

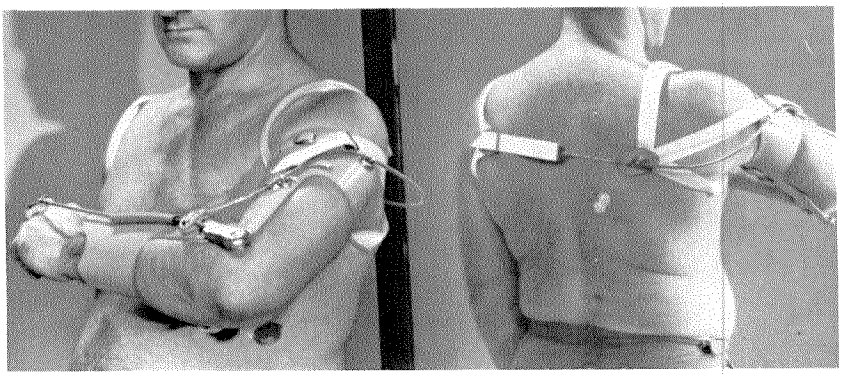

FIGURE 5. — Elbow orthosis with elbow lock.

Although the present device is quite bulky and resists changes in geometry and force (observe the inset miniature cylinder in the illustration), this problem is gradually being reduced as we learn the requirements of successful application.

C. Spinal-Cord-Injury Rehabilitation

1. *Environmental Control Systems*

a. *AMBRDL Random Access Environmental Control.* The AMBRDL (Army Medical Biomechanical Research & Development Laboratory) Random Access Environmental Control (Fig. 7) offers 14 channels. It comprises four units: a logic and control unit, a power transmission unit, a monitor unit, and an input interface unit. Multiple function outlets may be selected either by a coded input or by an automatic sequential mode.

The logic and control unit incorporates solid-state logic circuitry. A front panel ON/OFF toggle switch controls input power to the unit. The CODED/CLOCK switch selects the system operating mode: either a coded random-access mode or an automatic-sequencing (clock) mode. Four pushbutton switches are wired in pairs: one pair (OPERATE) permits a coded input and the second pair (SELECT) either activates or deactivates the selected environmental control channel (depending upon whether or not this channel has already been activated). An adjustment screw can be rotated to select the sequencing speed of the automatic sequencing mode.

The monitor unit contains 14 lamps, each associated with a random-access channel code and corresponding outlet.

The power transmission unit provides the appropriate input power for the various appliances being manipulated through the environmental control. A power and control section includes six 115V a.c. grounded re-

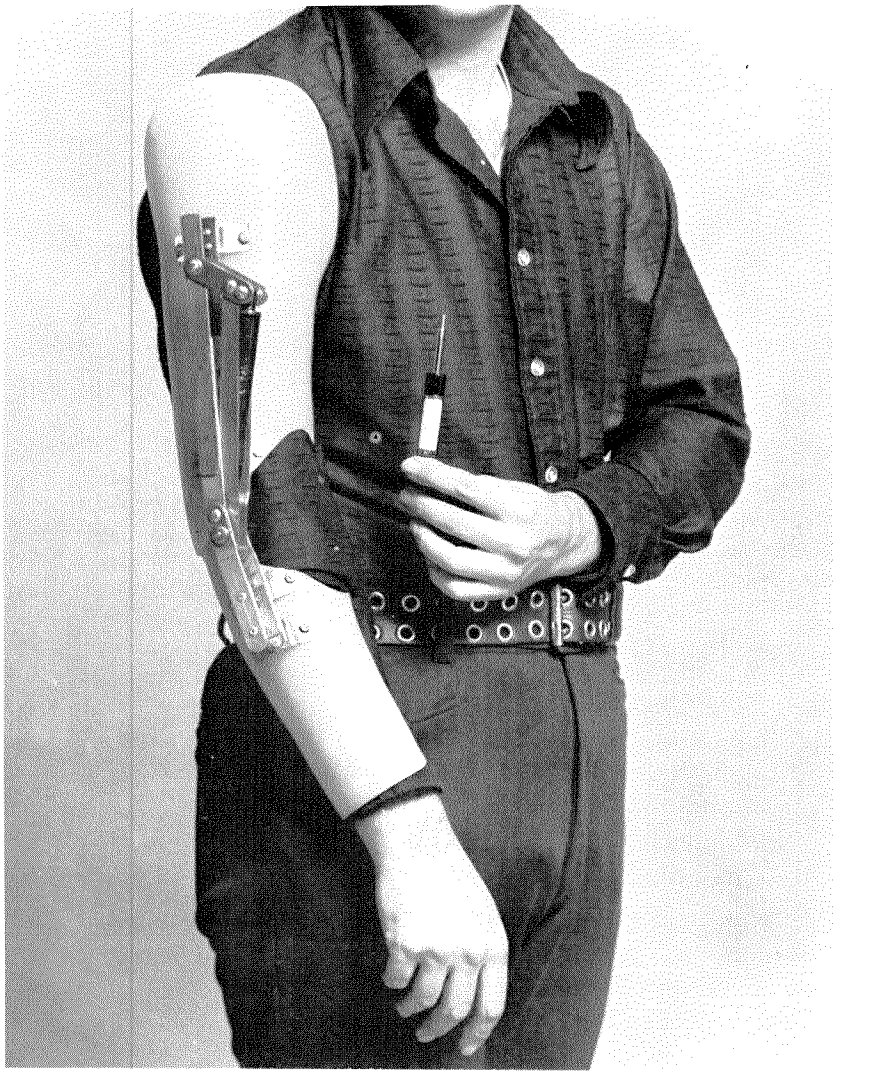

FIGURE 6.—Functional elbow orthosis with five-bar polycentric elbow linkage and miniature cylinder.

ceptacles, two full-time operational 115V a.c. grounded receptacles, and six momentary 12V d.c. outlets for controlling remote location relays. Two momentary simple-switching outlets are also available.

The input interface unit incorporates two pairs of pneumatic switches for breath control. Each pair is wired in parallel with the paired push-button switches located on the logic control unit front panel. These breath-control switches may be used as an alternative to the pushbutton switches for channel selection and activation.

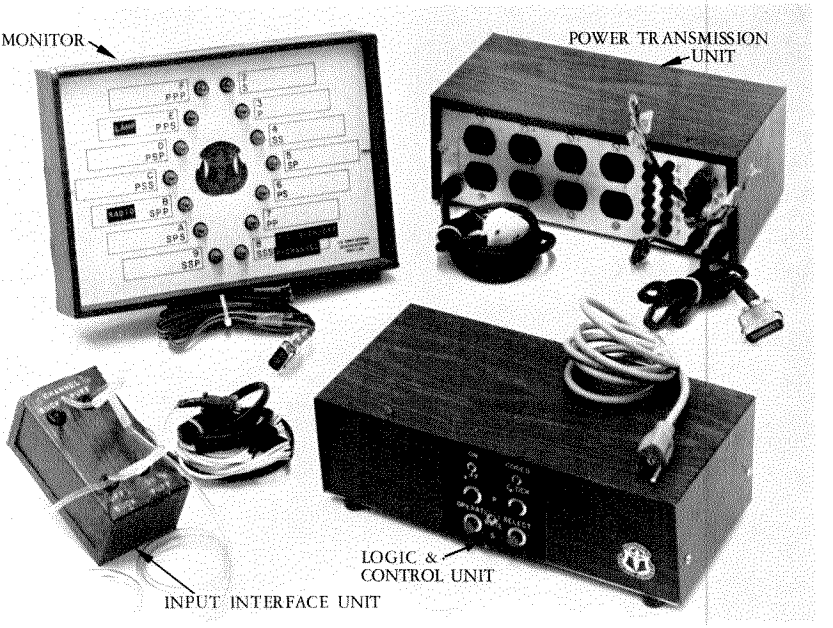

FIGURE 7. — AMBRDL Randon Access Environmental Control.

In the automatic sequencing (clock) mode, the environmental control automatically sequences in a clockwise direction if a positive pressure is generated in the channel-select breath-control tube, but sequences in a counterclockwise direction if a negative pressure is developed.

Thus far, the system has been clinically evaluated in the coded random access mode via breath control.

b. *Paratrol MK.* The Paratrol MK. II (Fig. 8) is a basic environmental control that was developed by the Prentke Romich Company of Shreve, Ohio. It permits a user to apply power to any combination of four grounded 120V a.c. power receptacles by using a single control switch.

To operate a given channel, a pushbutton switch is continuously depressed until the desired channel is sequentially selected. Channel sequence speed is controlled by rotating a small knob, located at the rear of the unit, to a desired setting. Selection is monitored by observing small indicator lamps located just above each power outlet. Releasing the pushbutton switch electrically activates a previously deactivated outlet or deactivates a previously activated outlet.

The Paratrol cannot control special adaptive appliances such as electric beds, motorized television tuners, and nurse calls.

The Paratrol has been under clinical evaluation at the Spinal Cord Injury Services in the Cleveland, Ohio, and Long Beach, California, VA Hospitals.

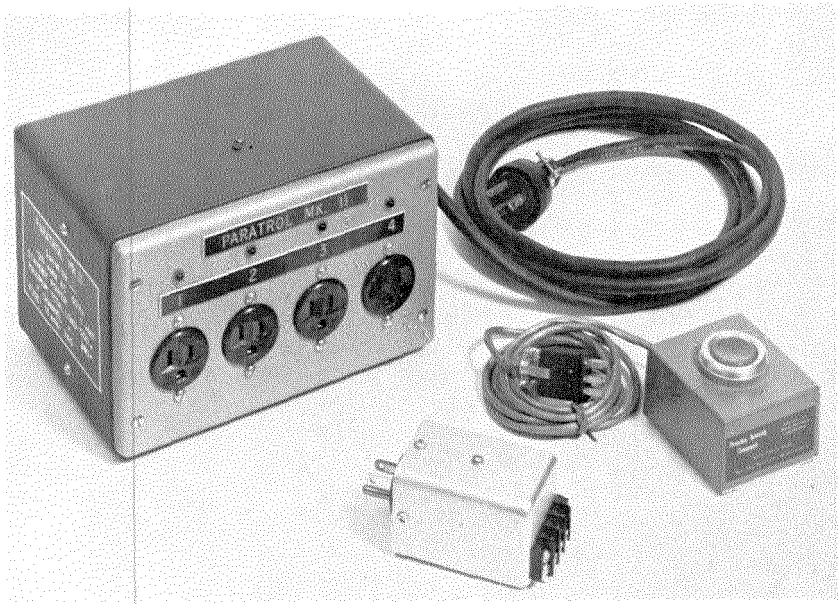

FIGURE 8. — Paratrol MK. II.

2. *Communications Aids*

a. *Microfiche Reader.* This is the third and final report in a series beginning in the Fall 1973 Bulletin (BPR 10-20), pages 294 and 295, and continued in the Spring 1974 Bulletin (BPR 10-21), pages 91 and 92.

Six prototypes (each identical to a laboratory model built by the VAPC) were made by General Teleoperators, Inc., of Paramount, California. These units were sent, for clinical evaluation, to various VA hospitals where they were used in libraries and Spinal Cord Injury Services. Reading material, limited and outdated, was from publications such as Time, Newsweek, and Readers Digest.

The consensus was that the outdated selection of reading material was undesirable due to lack of interest. Furthermore, the small screen (4 in. by 7in.) made reading difficult and required the reader to place his face close to the screen. The small size of the unit made for easy portability from patient to patient and its pneumatic controls made for easy use, but the low screen-brightness, non-uniformity of focus, and the recessed location of the screen and its orietation within the unit, were major problems.

We then acquired new Kodak Ektalite model 220 and 240 Microfiche Readers, which offered larger screens (approximately 8 in. by 11 in.) and higher levels of magnification (20X magnification for the Model 220 and 39X magnification for the Model 240). But upon reviewing these models in our laboratory, we concluded that microfiche readers were still unac-

ceptable. Despite the greater magnification levels and increased screen sizes, clarity was still unsatisfactory.

Therefore, our experience with microfiche readers suggests that they are still impractical and unsatisfactory for use by patients. The sparseness of popular, up-to-date reading material, the small screens and poor legibility, suggests that the current state-of-the-art in the development of microfiche readers for reading purposes is unacceptable. We have therefore decided to terminate development of the VAPC Microfiche Reader.

b. *PortaPrinter.* Initially conceived as a portable communication aid for a young boy suffering from cerebral palsy, the PortaPrinter (Fig. 9) is designed to scan and print alphanumeric characters from a matrix display. The unit incorporates two grounded power outlets for direct control of standard 115V a.c. electrical appliances.

FIGURE 9.—PortaPrinter.

Basically, the PortaPrinter is a communicator similar to the Tufts Interactive Communicator (TIC), described in the Spring 1975 Bulletin (BPR 10-23), pages 248 and 249. Specifically, the scanning function is quite similar, as is the matrix display of alphanumeric characters and the printout strip. Use of a single-pole, single-throw (SPST) actuating switch is also similar. The major communication difference between the TIC and PortaPrinter is that the TIC provides a limited selection of words and common combinations of letters (e.g., "ing"). The PortaPrinter provides the repetition on the display panel of certain letters of the alphabet (Fig. 9) to facilitate communicating speeds.

Portability is enhanced by its packaging within an attache case, but during battery power operation the device's limited environmental control capability is not available.

PortaPrinter's initial scanning mode is continuous in the vertical direction. When the row that contains the required letter or digit is illuminated, actuating the switch shifts the scan to a horizontal direction to reach the desired character. When the switch is again actuated, the selected character is printed on the paper tape and the PortaPrinter automatically returns to its vertical scanning mode.

In addition to the ability to activate self-contained 115V a.c. outlets, the PortaPrinter can receive commands to ring an alarm bell and operate an internal lamp to help read the printout strip.

There are additional features. A speed control dial is used to vary the scanning rate. The operator may turn off the PortaPrinter when not in use and maintain it in a standby mode to prevent battery drainage; the message board is inactive at this time. The nickel-cadmium batteries may be recharged.

One unit is now being evaluated in the Neurology Service at the Palo Alto VA Hospital.

3. *Wheelchairs and Accessories*

a. *A-BEC Electric Wheelchair.* Biddle Engineering Company, Ltd., of Halesowen, West Midlands, England, produces a family of folding electric wheelchairs that are marketed in this country through Abbey Rents Distributors, Los Angeles, California. The BEC-14 Rear-Drive Runabout and the BEC-12 Front Wheel Drive All-Purpose Runabout were evaluated in laboratory and clinical tests. The BEC-3, another front-wheel-drive product produced by this company, is quite similar to the BEC-12 and was therefore not evaluated.

FIGURE 10.—BEC-14 Electric Wheelchair.

FIGURE 11.—BEC-12 Electric Wheelchair.

The BEC chairs (Fig. 10 and 11) feature small motors, easily detachable lightweight batteries, and small wheels. They have semi-pneumatic, puncture-proof tires and automatic electric braking. They are easily foldable and portable. Their batteries (Fig. 12) have color-coded charge-indicator beads. The BEC-14 provides proportional speed control and direct rear-wheel drive without drive belts or other friction devices. In contrast, the BEC-12 employs a non-proportional microswitch-operated speed control and front-wheel drive.

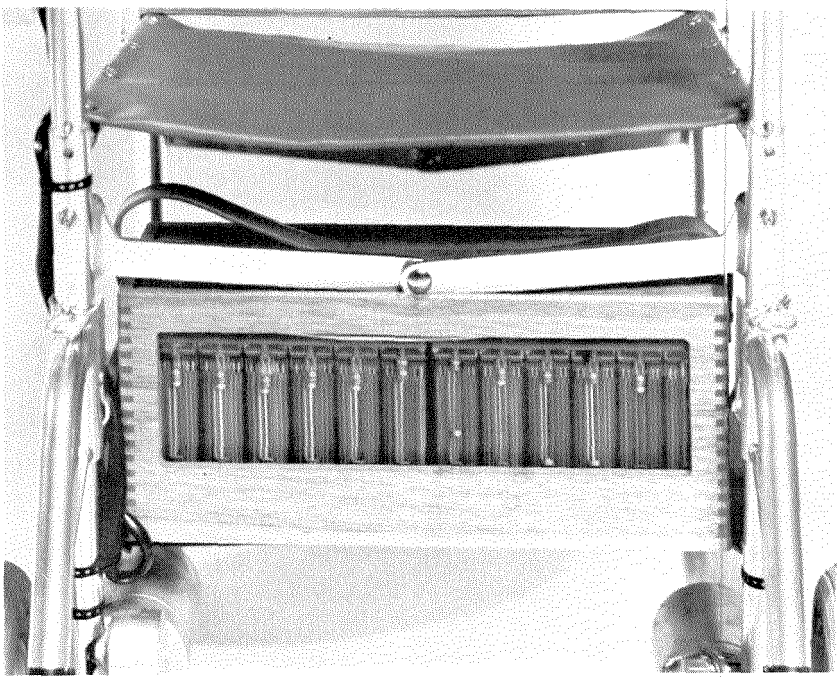

FIGURE 12.—BEC Wheelchair power units consisting of two 12V lead-acid batteries with color-coded charge-indicator beads.

Specially tempered and anodized lightweight aluminum is used to construct the wheelchairs. This provides corrosion-proof strength and durability. All moving parts of the drive systems are enclosed for protection from the environment.

If a malfunction occurs in the drive control system of either chair, a circuit breaker shuts off all power. To prevent inadvertent movement of the wheelchair when control power is removed, the wheels automatically lock in place.

Because its drive and control systems performed excellently, because its operation could be mastered with very short training periods, and

because the chair is lightweight, small, easily folded and stored, the BEC-14 was recommended for general use among veteran beneficiaries.

b. *Powered Wheel.* The concept of using powered wheels on electric wheelchairs and other electric vehicles has existed for several years. Although working laboratory models have been demonstrated by the Gar Wood organization in Miami, Florida, and by Dudley Controls in the United Kingdom, neither organization has succeeded in commercializing its designs.

Initially, the powered wheel was viewed as the ideal wheelchair drive. Friction drives, in contrast, cause accelerated tire wear and frequent tire gouging. Belt drives are subject to problems in adjustment and occasional failure. Drive chains can break, and unless they are carefully housed can have a dangerous tendency to catch clothing. Each of these drive systems is also vulnerable to outdoor environmental effects, particularly during periods of snow or rain.

The Photocircuits Division of Kollmorgen Corporation, Glen Cove, New York, markets a printed armature motor which results in a short-length stack; hence the name "pancake" motor. This motor has been described in the VAPC Research Report section of previous editions of the Bulletin (BPR 10-18 through BPR 10-24). Kollmorgen has now designed a powered wheel assembly around the printed motor, and two types of electric wheelchairs with separately designed motorized hubs have been built.

The first type incorporates a commercial Orbidrive transmission, the design of which is based upon the rotational relationship between two interlocked multiple-lobed cam and roller sets. One cam/roller set drives the other at a velocity that is proportional to the number of cam lobes and roller contacts in each set.

The second design is a more conventional spur gear assembly made by Kollmorgen's Photocircuits Division. A three-pass spur-gear reducer with a reduction ratio of 25:1 incorporates roller and ball bearings in a specially designed hub.

Superficially, the designs seem similar, but for a given power input the Orbidrive produces a lower speed and torque output, whereas the Photocircuits gear train develops greater speed and higher torque, and results in a smoother, more comfortable operation.

Both powered wheel units (Fig. 13, 14, and 15) have similar steady-state battery current drain of between 5A and 10A. A 24V power source permits maximum speeds of up to 5mi/h (8km/h). The Orbidrive system cannot climb an incline steeper than 6deg with a 165-lb (72.57kg) occupant; the Photocircuits system can climb an incline of 8deg under the same conditions. Each wheelchair type has a modular electrical system that includes motors, an electronic controller, and a proportional joystick assembly. Both units are undergoing tests at VAPC, and clinical evaluation at various VA Hospitals.

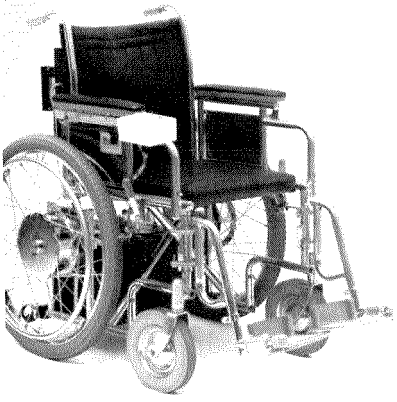

FIGURE 13.—Wheelchair with powered wheel, front view (typical for both designs).

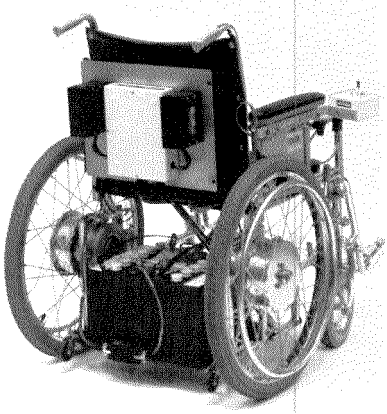

FIGURE 14.—Wheelchair with powered wheel, rear view (typical for both designs).

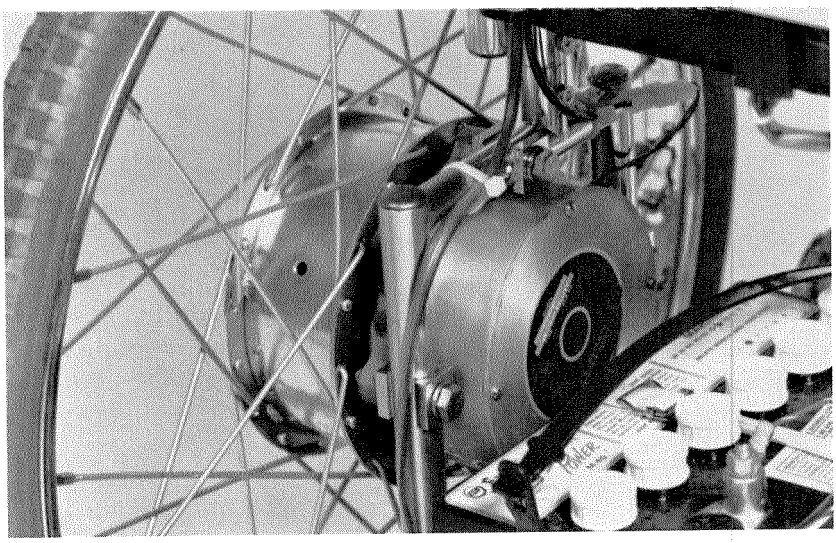

FIGURE 15.—Powered wheel, close-up view (typical for both designs).

c. *VAPC Electric Wheelchair Battery Tester.* Because wheelchair manufacturers generally design power packages around easily available standard battery case sizes, automotive lead-acid batteries are by far the most common in electrically powered wheelchairs. But automotive batteries, by design, deliver high electrical currents for limited durations

immediately followed by recharge periods. They are not ideal for electric wheelchair use because electric wheelchairs do not demand substantial current discharge rates; instead they require deep discharges during daily use.

Electric vehicle batteries have proved to be excellent power sources for wheelchair use. Unfortunately, they are not readily available in popular wheelchair battery sizes, such as the number 22 and 24 cases.

With few exceptions, automotive batteries tend to fail prematurely (sometimes quite suddenly) when used in powered wheelchairs. To counter this problem, the VAPC has developed a battery tester that simulates a realistic electric wheelchair load on a battery, and can disclose the battery's electrical condition during testing.

The VAPC Electric Wheelchair Battery Tester (Fig. 16) uses two built-in meters (15V d.c. and 50A d.c.) and an indicator lamp to determine if the battery is sufficiently charged, and if it is defective or nearing the end of its useful life. This is accomplished with a "dummy" wheelchair electrical load applied to the battery, which should then deliver approximately 40A at 12V. If the battery deviates significantly from this 40A, 12V guideline, the battery either requires a charge or is defective: recharging the battery and subjecting it to a second test determines if it is defective.

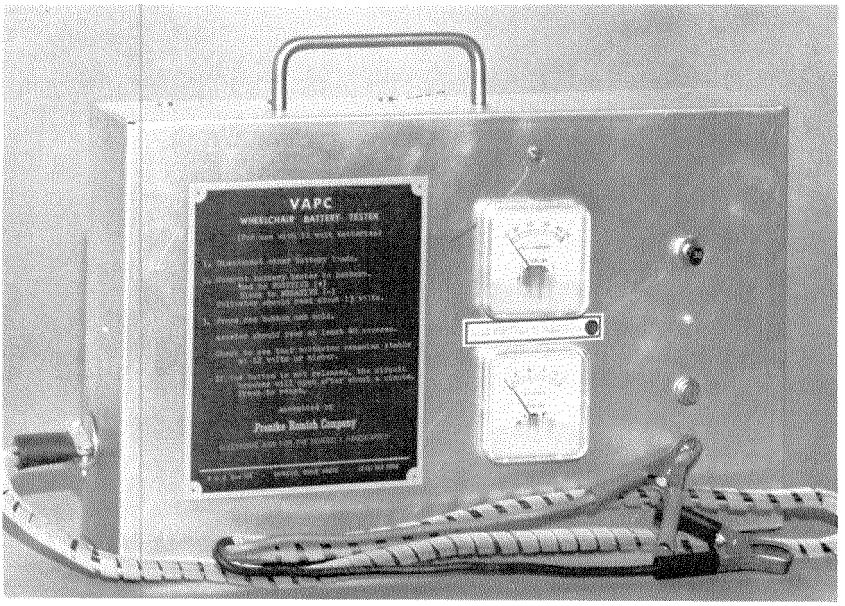

FIGURE 16. —VAPC Elecric Wheelchair Battery Tester.

Battery tester types include specific gravity indicators and individual no-load cell testers: VAPC has determined that these techniques are generally unreliable and inconvenient. Also, it is inappropriate to subject wheelchair batteries to standard automotive battery tests, which demand inordinate electrical discharges. The VAPC wheelchair battery tester is intended to be simple, reliable, and convenient. Several units are now being used in clinics and wheelchair maintenance facilities for evaluation.

d. *BykFil Rubber Compound.* BykFil (Fig. 17) is a soft rubber compound that is injected into the inner tube of a wheelchair tire to make the tire puncture-proof. The compound replaces the air in the tire by completely filling the inner tube while the tire is mounted on the wheel. Hardness is controlled to simulate the desired pressure of an air-filled tire.

The material reaches a cured state approximately 24 hours after filling. When the tire wears down, tire, tube, and filler are removed by cutting them away from the rim and a new tire and inner tube are assembled on the rim. The BykFil process can then be repeated.

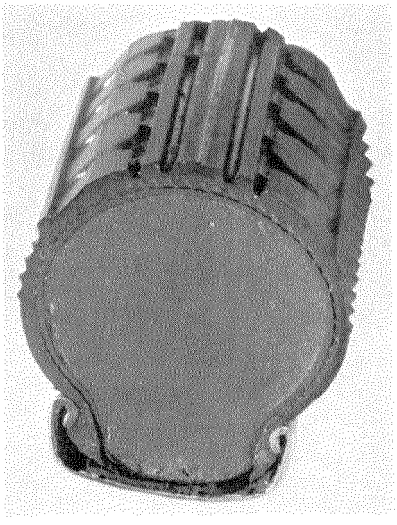

FIGURE 17.—Bykfil Rubber Compound: the solidified material is shown filling what is normally the air space, in this cross-sectional view of a pneumatic tire, tube, and wheel rim.

SynAir of Tustin, California, developer and manufacturer of BykFil, has established contact with several wheelchair manufacturers who will incorporate use of the compound with their products.

Limited field tests have thus far shown the product to be desirable, despite the additional weight of a BykFil-modified tire (a 24in. x 1¼in. diameter tire weighs approximately 2 lb more when filled with BykFil compound to simulate 50 psi tire pressure). Rolling resistance is virtually identical to that of a pneumatic tire, and superior to a standard hard-rubber tire.

Tires filled with the BykFil compound have been evaluated at several VA hospitals, and by members of the EPVA (Eastern Paralyzed Veterans of America) with excellent results. Apparently, the added weight of the BykFil does not affect the transfer of a paraplegic into an automobile. Our evaluation suggests approval of BykFil for general use within a few months.

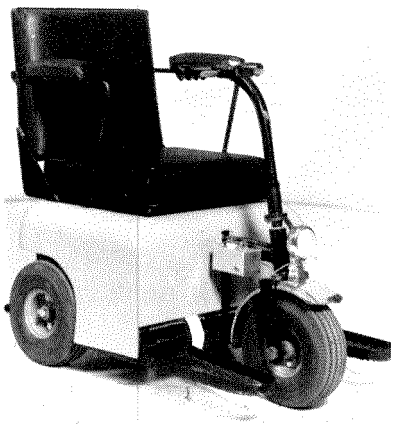

FIGURE 18. – Tri-Wheeler.

e. *Tri-Wheeler.* The Tri-Wheeler (Fig. 18) is a three-wheel battery-powered cart available from the Braun Corporation in Winamac, Indiana. It has four speed ranges that permit level ground speeds of 1.4, 2.6, 3.9, and 6.2 mi/h (2.3, 4.2, 6.3, and 10.0km/h). Like other battery-powered carts previously evaluated by VAPC, its 24V power source provides drive speeds in excess of 6 mi/h (9.7km/h) and allows it to climb inclines beyond 12 deg. In addition, as with carts tested previously by VAPC, the Tri-Wheeler incorporates a headlight, a taillight, and a pushbutton-controlled horn. It also employs an automotive-type differential which the manufacturer claims provides maximum traction over bumps, and through snow, sand, and mud.

Its physically small size and short turning radius give it a significant advantage because, unlike other battery-powered carts, the Tri-Wheeler can be maneuvered indoors. This vehicle is presently undergoing clinical evaluation at a nearby VA hospital.

f. *Naval Electronics Laboratory Center Stand-Up Wheelchair.* This is a report on the first phase of a three-phase program that envisions the design and development of a three-module system consisting of the electrical stand-up wheelchair (Fig. 19 through 22), a free-roving ambulator, and a compatible licensed vehicle.

FIGURE 19. — Stand-Up Wheelchair shown in position to receive its occupant.

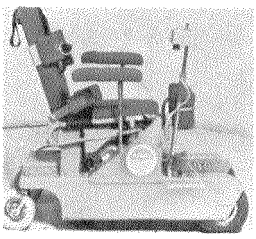

FIGURE 20

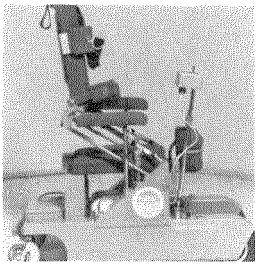

FIGURE 21

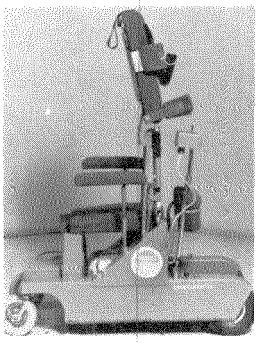

FIGURE 22

Stand-Up Wheelchair shown in the sit-down mode (Fig. 20), in a partially raised position (Fig. 21), and in the stand-up mode (Fig. 22).

Produced by the Naval Electronics Laboratory Center under a VA purchase order, the stand-up wheelchair is a joystick-controlled electric wheelchair with a built-in powered mechanism that can raise a seated occupant to an erect position from which he is still able to control the unit. Initial evaluations were performed by the Bioengineering Research Service of the VA Prosthetics Center in New York City, and subsequent

clinical applications were conducted by the VAPC Clinical Evaluation Service at the VA Hospital, Castle Point, New York.

A consensus reached by N.E.L.C. personnel (who conducted the initial performance studies) and key VAPC personnel was that, potentially, the stand-up wheelchair is a significant first step in the total three-phase program. With certain modifications, which will be incorporated by N.E.L.C., the stand-up wheelchair can be useful in the home, for various vocational and educational facilities, and for certain recreational pursuits. Four revised units will be fabricated by N.E.L.C. and then evaluated by VAPC.

4. *Beds, Lifts, and Other Aids.*

a. *Reyer Lift.* This device is manufactured by Wilch Manufacturing, Inc., of Topeka, Kansas. Mr. Reyer, the inventor, claims that the Reyer Lift is the first self-operating battery-powered lift for invalids. It consists of a hoist and transport apparatus intended to enable invalids and disabled persons such as paraplegics and polio victims to transfer themselves to and from beds, toilet seats, bath tubs, and wheelchairs. Mr. Reyer further claims that the device is adjustable for all bed heights, that it is safe, and that disabled persons using it can be self-sufficient.

Structurally, the Reyer Lift consists of a metal frame with vertical supports placed at the head and foot of the bed, with a horizontal overhead support that contains the mechanism for lifting and transferring the individual. Two motors with corresponding independent transmissions provide the required vertical and horizontal positioning of a built-in patient-carrying boom. The motors are powered by two 12V automotive batteries connected in parallel. The patient controls the position of the boom with two electromechanical momentary switches located inside a control box attached near the support end of the boom (for easy access). There is no harness used with the Reyer Lift.

Literature and photographs of the Reyer Lift were independently reviewed and studied by laboratory and clinical personnel. As a result of this study, a number of apparent deficiencies were revealed and brought to the attention of the manufacturer.

b. *Sanyo Hydraulic Walker.* The Sanyo Hydraulic Walker (Fig. 23) is manufactured by Sanyo International, Inc., of Tokyo, Japan. According to the manufacturer, the device supports patients who require assistance when walking, and enables them to walk up or down steps, inclines, ramps, and curbs as well as on level ground. A hydraulic system controlled by hand levers allows the legs of the Walker to be adjusted to differences in individual heights. To achieve the proper height, fluid is inserted into the legs of the device by means of a syringe and ball-check valve system (Fig. 24). The device is lightweight, compact, collapsible,

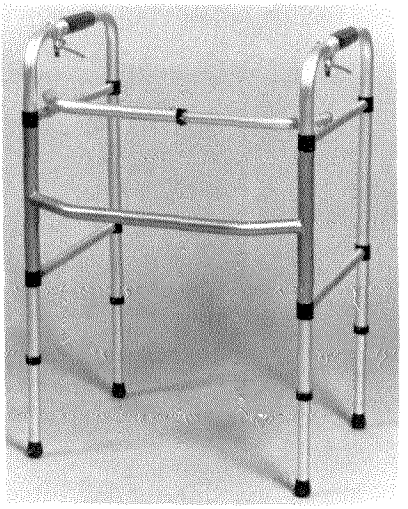

FIGURE 23. — Sanyo Hydraulic Walker.

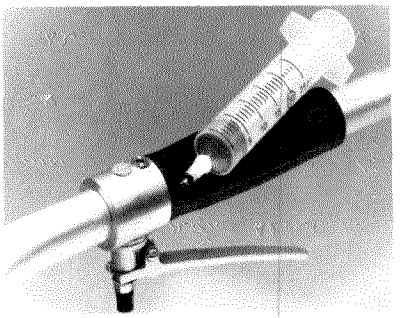

FIGURE 24. — Insertion of fluid into legs of Sanyo Hydraulic Walker by means of a syringe and ball-check valve system.

easily stored, and well constructed. One size conveniently adjusts to any user.

A clinical evaluation of the Sanyo Hydraulic Walker was conducted by the VAPC Rehabilitation Medical Staff at the Va Hospital, Castle Point, New York. Ten patients used the device in the clinic. It was found to be lightweight and required little energy in walking. It provided a level, sturdy base of support for level surfaces and for climbing stairs, curbs, and inclines. The consensus was that the hand lever required only minimal hand strength for adjusting leg length.

It was recommended that the Sanyo Hydraulic Walker be made available for VA beneficiaries on prescription.

c. *Speedo Aqualift Swimsuit.* The Speedo Aqualift Swimsuit (Fig. 25) is manufactured by Blue Grass Industries, Inc., of Carlisle, Kentucky. It is a one-piece swimsuit, designed for use by both beginning and physically handicapped swimmers, that can support adults up to 200 lb in weight. A quick-drying nylon tricot fabric, identical to that used for Speedo's racing swimsuit wear, is used to make the swimsuit. An inflatable air bladder, built inside the front of the suit, can be inflated by depressing a valve and then blowing into the mouthpiece of the valve (very little air is required). With the valve nut turned fully clockwise, the air is prevented from accidentally escaping.

FIGURE 25.—Speedo Aqualift Swimsuit with optional flotation collar.

An optional flotation collar that fits around the neck (operation of the flotation collar is identical to that of the air bladder) is also available. It features a Velcro closure that attaches to the swimsuit.

Different styles and sizes are available for girls, boys, women and men. Chest measurement determines size. The swimsuit is designed not to be a life preserver, but as an aid to swimming instruction for both beginners and the physically handicapped. It should therefore be used with proper supervision and normal standards of water safety.

Eight of the swimsuits were tested and evaluated at VA Hospital, the Bronx, New York and VA Hospital, Wood, Wisconsin, under the supervision of the therapist in charge of the hydrotherapy program at each hospital. At the VA Hospital in the Bronx, several patients, some of whom were at first apprehensive, gained a large measure of confidence and pleasure by using the swimsuits. At the VA Hospital in Wisconsin, the cosmetic appearance of the suit bothered some, but they were a minority. A greater problem was the size of the neck opening, which was originally designed for children. Thus a larger neck-opening size is needed. Also, some patients found it difficult to breathe when the suit was inflated:

reducing the air pressure solved that problem. Finally, some patients tended to roll over when swimming on their backs. Accessory flotation packs attached to the swimsuit would compensate for this problem. Accessory flotation packs could also help low level paraplegics and quadriplegics gain buoyancy of their pelvis and lower limbs.

The flotation collars are now being used as pillows in Hubbard tanks.

Generally, the Speedo Aqualift Swimsuit was found useful in stimulating and teaching swimming techniques to handicapped veterans, and was thus recommended to be made available for VA beneficiaries.

d. *ConVaid Mobile Prone Stander 4000.* The ConVaid Mobile Prone Stander 4000 (Fig. 26 and 27), manufactured by the ConVaid Company of Palos Verdes, California, is an institutional rehabilitation aid that offers a new concept in prone support and weight-bearing. It combines characteristics of the tilt table, gurney, and prone board with the independence of self-propulsion.

Benefits derived from its use, as claimed by the manufacturer, are as follows: assists in strengthening back and neck muscles, prevents contractures or hip dislocations, develops the upper limbs, assists bowel and bladder function, aids digestion, inhibits bone decalcification, promotes bone growth in children, relieves pressure on decubitus ulcers, assists circulation, and provides mobility for the patient. In addition, the work surface provided by an adjustable built-in tray is potentially useful for various activities.

It features a power tilt adjustment, universal drive, easy-care upholstery, dual self-adjusting brakes, the built-in tray described above, and

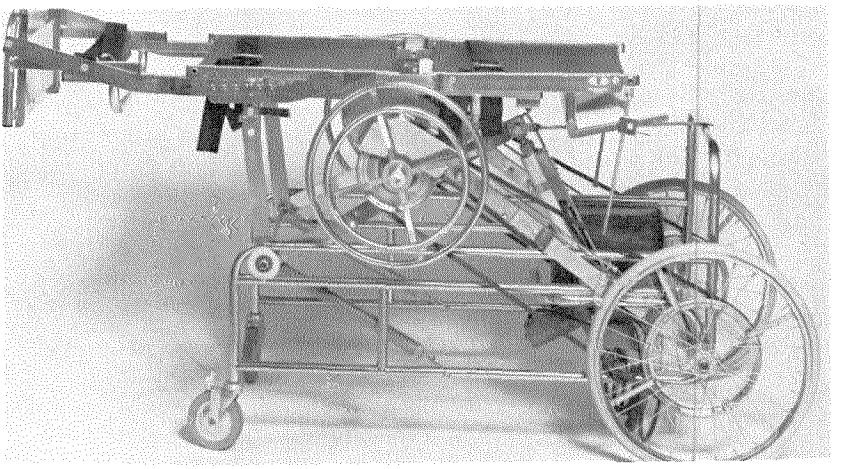

FIGURE 26.—ConVaid Mobile Prone Stander in the prone position.

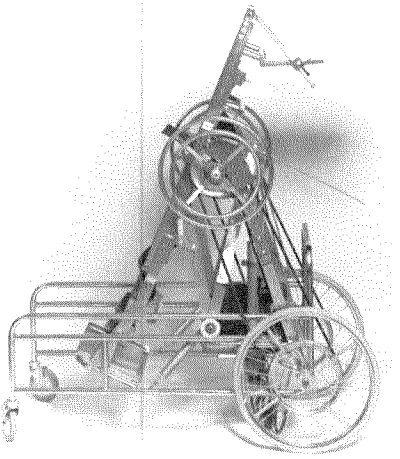

FIGURE 27.—Convaid Mobile Prone Stander in the stand-up position.

hand-wheel rims specially designed to drop below the level of the side frame when the device is set in its horizontal or prone position: this allows easier patient transfer.

The patient litter frame, which is constructed of welded, cold-rolled steel tubing and bar stock, is raised or lowered by an electromagnetic screw jack that has a 5-sec thermal overload switch and a 10-sec automatic reset switch. The maximum load-lifting capacity of the jack (as rated by the manufacturer) is 500 lb, and a maximum of 70 deg of frame elevation can be attained. This permits the user to achieve approximately 92 percent of weight-bearing. A built-in hammock support of vinyl-coated nylon fabric, with tension adjustment, provides the cradling effect required for proper body alignment of heavier patients.

The universal drive provides two-arm propulsion that can easily be converted to either left or right one-arm drive. Of the two hand rims on either side of the gurney, the outer pair is used for bilateral upper-limb propulsion. By manipulating a coupler on the outer hand rim, the system may be converted from bilateral to unilateral propulsion. A 41A, 12V battery provides power for the elevating system.

A demonstration of the device at the Spinal Cord Injury Service in the VA Hospital, Castle Point, New York, provided instruction in its use for the nursing staff and selected patients. Two paraplegic patients were selected to use the device: a T7 injury level patient, and a L3/L4 injury level patient. The T7 patient used the device for 3 days (total time of 24 hours), after which his medical condition improved sufficiently to warrant its discontinuation. The L3/L4 patient used the device daily (4 to 6 hours a day) as an adjunct to his scheduled therapy, for weight-bearing at

maximum angulation. In the upright position, he was able to study, read, and participate in various recreational activities; and he was able to propel the gurney from either the prone, intermediate, or upright position as he traveled through the ward.

Although the ConVaid Mobile Prone Stander 4000 was well received by medical staff and patients as a useful rehabilitation aid, several features were found to need improvement to meet minimal requirements for standing aids.

e. *Therapeutic Wheelchair Rocker.* The Therapeutic Wheelchair Rocker (Fig. 28) is manufactured by Wojcik Industries, Inc., of Fallbrook, California. The manufacturer claims that his chair produces several therapeutic benefits for those handicapped persons confined to wheelchairs who use it: it aids circulation; improves balance and coordination; prevents decubitus ulcers on the buttocks; provides therapeutic benefits for the neck, shoulders and abdominals; assists proper breathing; assists digestion; and affords psychological benefits by simple diversional relaxation through natural, spontaneous exercise.

The wheelchair rocker is constructed of two baked-on-enameled alum-

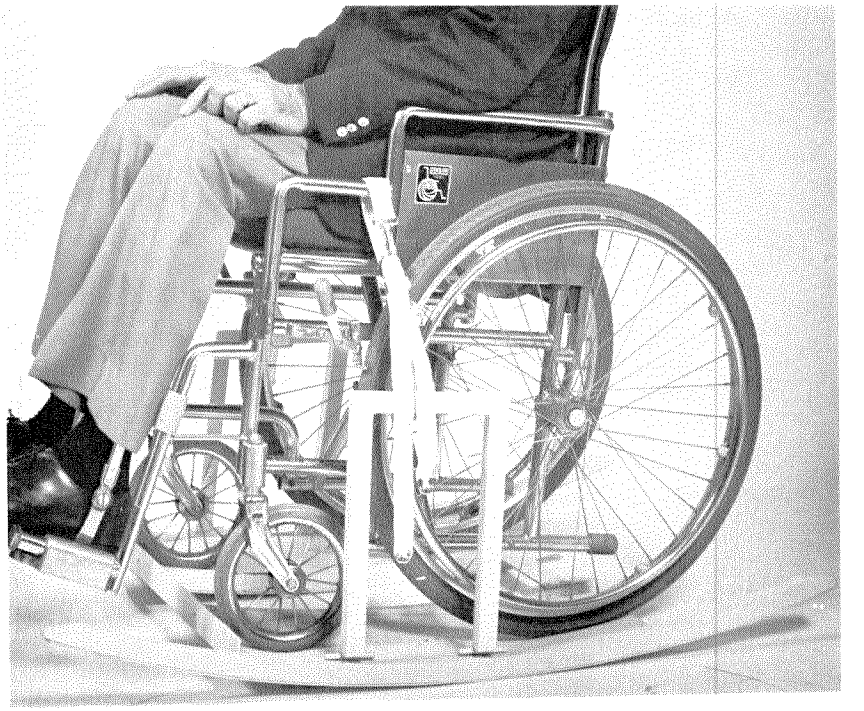

FIGURE 28. — Therapeutic Wheelchair Rocker.

inum rocking platforms connected together. Wheelchairs that measure 18 to 27 in. in overall width can be used. Hinged frame extensions, attached midway on both outermost rockers, are used in conjunction with canvas straps to secure the wheelchair to the rocking frame.

The rocker is approached from the rear: the confined person elevates the front casters of his wheelchair slightly while maintaining forward momentum to get his wheelchair onto the rocking platform. (A second individual may help by lowering the rear of the rocker to allow the confined person to push his wheelchair onto the platform.) The wheelchair is moved forward until it is completely on the platform; the front casters will then be hitting the limit stops placed at the front end of the rocking platform. The occupant's next step is to lock the wheelchair brakes and secure the wheelchair to the rocker frame by tightening the canvas straps to his wheelchair armrests. Then, by moving the upper part of his body continuously forward and backward, he produces the rocking motion.

Evaluation by clinical observation only was required because the simple construction of the Rocker did not warrant laboratory testing, and only its usefulness as a relaxation device was evaluated. This evaluation was conducted by members of the Eastern Paralyzed Veterans Association, and by the Nursing Home Care Unit, and Activities of Daily Living Room, Rehabilitative Medicine Service, at the VA Hospital, Castle Point, New York. Wheelchair-confined individuals were able to use the rocker as desired. Enthusiastic responses that depicted the rocker as a relaxation aid were made by most of those who tried it.

As a result of the clinical evaluation, it was apparent that the device was of benefit as a relaxer for the wheelchair-confined person. The Therapeutic Wheelchair Rocker is recommended for veteran beneficiaries requiring such an item at this time. Further observation of geriatric patients during its initial use should indicate whether the Rocker should be recommended for those persons as well.

f. *The Wayne Chair.* The Wayne Chair (Fig. 29 through 31), manufactured by the Wayne Chair Company of Warren, Michigan, combines the three functions of a manually propelled wheelchair, a commode chair, and a shower chair.

According to the manufacturer, the Wayne Chair is the only collapsible, manually propelled wheelchair now in existence that can be converted to a commode chair while the patient is sitting in it, and wheeled over the commode. The chair can be converted back for regular use while the patient remains sitting in the chair, completely eliminating the need for lifting or handling the patient in any way. It can also function as a shower chair because the lower portion of the back can be opened to give the patient more freedom to bathe.

The Wayne Chair is a standard size wheelchair with 23-in. solid rubber

FIGURE 29. — The Wayne Chair used as a manually propelled wheelchair.

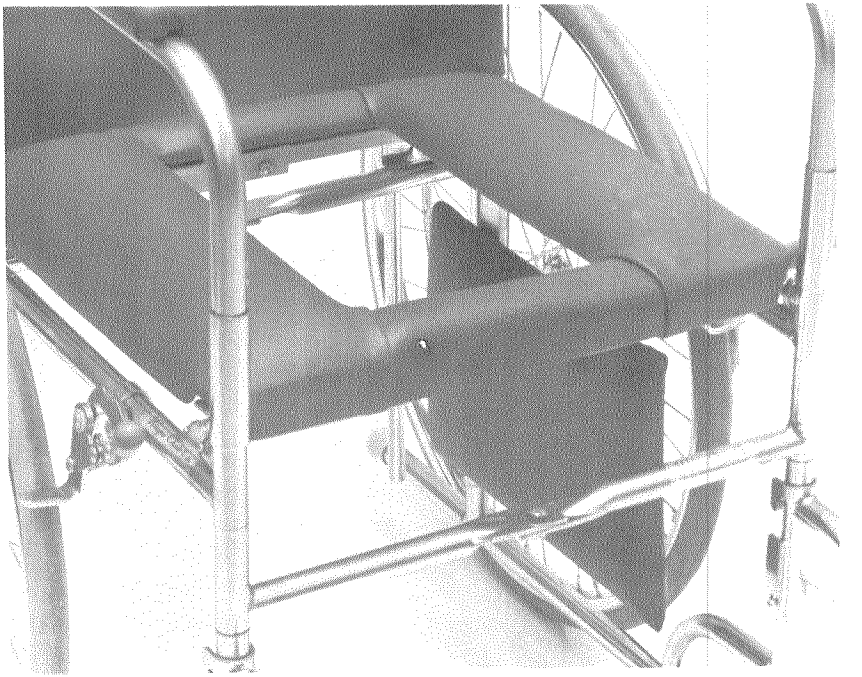

FIGURE 30. — The Wayne Chair used as a commode chair.

rear wheels, 8-in. solid rubber front caster-wheels, 15-in. seat depth, 17-in. seat width, 22 in. from seat to floor. It has over-center toggle breaks, and detachable leg rests. Metal parts are chrome-finished to resist rusting. Its fully padded seat and solid structure make it comfortable to sit in. Armrests are completely padded. The back of the chair is padded on both sides so that the patient's shoulders do not come in contact with metal at any point. (The back also has an opening to install safety straps.) All padding is covered by washable, waterproof upholstery.

The Wayne Chair also has swing-away arms; the arms swing around to the back of the chair, making it easier to transfer the patient from bed to chair or from chair to bed. Also, the chair can be wheeled closer to a table with the arms in the rear position, thus making it easier to seat the patient comfortably at a table. The arms are permanently attached to the chair to make it impossible to misplace or lose them; when used as arms, they lock in place.

As there are no applicable VA standards for multi-purpose wheelchairs, the Wayne Chair was evaluated functionally by demonstrating it and putting it into day-to-day nursing service in the wards of the Spinal Cord Injury Service and the Nursing Home Care Service in the VA Hospital at Castle Point, New York. In addition, the Wayne Chair was evaluated by a disabled person in his home. This report is based on information gathered from its use by personnel with patients in these services, and the one outpatient. The wheelchair was not subjected to destructive testing.

In general, the Wayne Chair functioned quite well as a manually propelled wheelchair. Comfort was particularly singled out for comment by most users. The nursing staff, however, reported that it was difficult to swing the armrests away when close to the transferring surface; one has to remember to swing them away before approaching an object.

When using it as a commode chair, some difficulty was experienced by attendants in closing and locking the hatch. None of the patients could independently open the commode hatch, perform personal hygiene, then close and re-lock the hatch. Moreover, the large wheels prevented the occupant from having access to his anus; in all cases, an attendant had to perform this task.

Several areas of rust were detected. While these rust areas did not impair the functioning of the chair, rust may not be acceptable cosmetically by some. The manufacturer, when advised of this, reported that several of these chairs were being used in VA Hospitals with no evidence of rusting.

In summary, the Wayne Chair has a practical application to the needs of some VA beneficiaries. It is unsatisfactory for independent personal hygiene use, but because of its uniqueness, we recommend that it be made available on prescription for veteran beneficiaries.

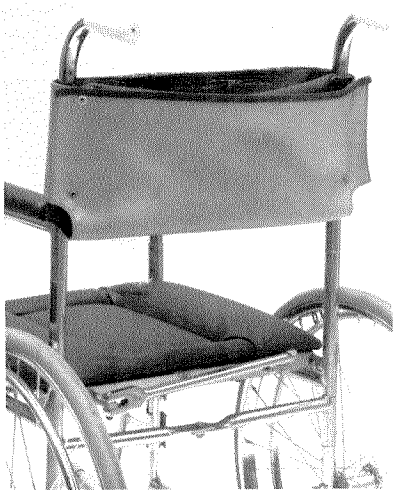

FIGURE 31.—The Wayne Chair used as a shower chair.

5. *Automotive and Driving Aids.*

a. *VA Standard Design for Safety and Quality of Automotive Adaptive Equipment VAPC-A-7505-8.*[a] Following is the VA Standard Design and Test Criteria for Safety and Quality of Special Automotive Driving Aids (Adaptive Equipment) for Standard Passenger Automobiles (VAPC-A-7505-8):

1.0 *Scope, Classification, and Limitations*—1.1 *Scope* These standards relate to special automotive driving aids (adaptive equipment), other than those provided by the automobile manufacturer, for operating passenger automobiles used by handicapped drivers. Maximum safety and suitablility to drivers and the general public is of primary concern.

1.2 *Classification.* Special automotive driving aids (adaptive equipment) includes a variety of devices to enable handicapped persons to drive automobiles. Devices covered in this standard are those specifically needed for safely operating an automobile as follows:

SPECIAL AUTOMOTIVE DRIVING AIDS REQUIRED FOR LOSS OR PARALYSIS OF LIMB

Special automotive driving aids required	Right leg	Left leg	Both legs	Right arm	Left arm
A. Brake and accelerator			X		
B. Dimmer switch	X	X	X		
C. Left foot accelerator	X				
D. Parking brake		X	X	X	X
E. Steering assists[1]				X	X
F. Turn lever, right hand operated					X
G. Shift lever, left hand operated				X	

[1] Steering assists are add-on devices for use with standard automotive steering wheels, e.g., Spinner Knob, Quad Grip, Flat Quad Spinner, Open-Top Quad Spinner, Latch-Type Quad Spinner, Ring-Type Spinner, Yoke-Type Spinner, etc. These items might be useful to disabled drivers with nearly average upper extremity strength and mobility, but who require some assistance in steering a motor vehicle.

1.3 *Limitations.* These standards are limited to those hand control systems and devices and the foot control shown in 1.2 above. Passenger vehicles equipped with hand controls should also be equipped with an automatic transmission, with or without power steering, and with or without power brakes.

2.0 *Applicable Documents*—2.1 *Federal Motor Vehicle Safety Standards.* Federal Motor Vehicle Safety Standards were not originally promulgated to apply to the variety of special equipment used by handicapped drivers. Because the following FMVSS's establish desirable measures for adaptive automotive equipment they are interpreted in the document to cover *all* drivers.

2.1.1 *FMVSS No. 101* requires that all essential controls be within reach of the driver when restrained by a lap belt and upper torso constraint, and that these controls be appropriately identified.

2.1.2 *FMVSS No. 105* specifies requirements for hydraulic service brake, emergency brake, and parking brake systems intended to provide adequate braking performance under normal and emergency conditions.

2.1.3 *FMVSS No. 107* specifies that automobile surfaces which are in a position to reflect sunlight into the driver's eyes shall have a dull finish.

2.1.4 *FMVSS No. 124* establishes requirements for the return of a vehicle's throttle to the idle position when the driver removes his foot from the accelerator control, or in the event of a breakage or disconnection, in the accelerator control system.

2.1.5 *FMVSS No. 201* requires protection from internal impact, generally through the elimination of sharp surfaces and the use of padding. Adaptive control equipment installed to an automobile shall not diminish the effectiveness of existing internal protection, and shall be padded or otherwise designed to minimize injury to the driver or passenger upon impact.

2.1.6 *FMVSS No. 203* requires that steering systems yield forward in the event of frontal impact to minimize injuries to the driver.

2.1.7 *FMVSS No. 302* specifies the use of burn resistant materials in passenger compartments.

2.2 *Society of Automotive Engineers Stnadards and Recommended Practices.* SAE Standard J575(e) Test for Motor Vehicle Lighting Devices and Components (Corrosion Test, ASTM B117). SAE Recommended Practice J556 Automobile Wiring.

3.0 *Tentative Veterans Administration Standards*—3.1 *Qualifications.* Special automotive driving aids provided by the VA for veteran users shall be qualified by tests conducted periodically at VAPC. The tests set forth in the following sections shall be applied.

3.2 *Major Components.* Among major components to be tested are:

(a) Linkages.

(b) Terminal Brake and Accelerator Connectors.

(c) Control Lever.

(d) Attachment Hardware.

(e) Accessories, including Dimmer Switch, Horn Button, or any other adaption designed to operate automotive auxiliary equipment.

3.3 *Strength of Materials*—3.3.1 *Standard.* All components shall be constructed to prevent permanent deformation under the stress of normal usage which varies greatly depending on whether power brakes are used.

3.3.2 *Specification.* Fully assembled and installed hand control systems limited to motor vehicles with power brakes shall not be permanently deformed under a static load of 62.5

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[a]Some material has been added to these Criteria since publication in the Federal Register, Vol. 40, No. 65—Thursday, April 3, 1975. For example, some tests of braking systems now include sets of values appropriate for vehicles with power brakes and for vehicles with manual brakes.

lbs. (278 newtons) applied to the handle of the Control Lever. Hand control systems for cars without power brakes shall meet the same requirements under a static load of 150 lbs. (667.2 newtons) applied to the handle of the Control Lever (FMVSS 105).

3.3.3 *Tests.*—3.3.3.1 *Test 1.* A static load of 62.5 lbs. (278 newtons) is applied to the handle of the Control Lever to simulate brake actuation of the adaptive system for vehicles with power brakes. For vehicles without power brakes a static load of 150 lbs. (667.2 newtons) is applied to the handle of the Control Lever. The load shall remain on the Control Lever for a period of 30 to 35 seconds. Changes in alignment or deformation shall be determined by inspection and measurement.

3.3.3.2 *Test 2.* Fatigue life is simulated in the laboratory applying 80% of the 62.5 lb. proof load, i.e., a 50 lb (222.4 newton) force 250,000 times to actuate the brake control, and a 10 lb. (44.48 newton) force to actuate the accelerator control of an assembled hand control system. These forces are applied to the handle of the control lever. One (1) complete cycle of brake or accelerator actuation shall be accomplished in 0.5-1.0 seconds to simulate average time responses required in driving an automobile. For controls designed for use on vehicles without power brakes, fatigue life is simulated by applying 80% of the 150 lb. proof load, i.e., a 120 lb. (533.8 newton) force to actuate the brake control in a manner similar to the requirements given for power brake type hand control systems. Periodic inspection of the test in intervals of 50,000 cycles are made, and changes in alignment, wear, or loosening of fasteners are recorded.

3.3.3.3 *Test 3.* In cases where Test 2 is not feasible (e.g., individual components or linkage sub-assemblies), acceptable strength is verified by generating a 4.6 g load (2.54 mm displacement at 30 Hz, i.e., $\pm$1.27 mm from zero reference) through the text sample on a laboratory shaker. The vibratory motion is maintained for 2 hours in each the axial and transverse direction of assembly. Components that could be adversely affected by the heat produced at 30 Hz (e.g. rubber parts) shall not be included in this cyclic test.

3.4 *Resistance to Corrosion*—3.4.1 *Standards.* All components of adaptive automotive driving aids shall be resistant to corrosion. In addition, the provisions of FMVSS No. 107 in regard to "specular gloss" shall apply. All components shall be plated or otherwise treated with glare-free industrial finishes. Each system or device submitted for evaluation shall be accompanied by a statement describing the finish material and process.

3.4.2 *Test 4.* A fully assembled sample unit shall be subjected to a salt spray (fog) test in accordance with the latest ASTM B 117, Method of Salt Spray (Fog) Testing, for a period of 50 hours, consisting of two periods of 24 hour exposure and 1 hour drying time each. (Reference SAE Standard J575 (e) "Test for Motor Vehicle Lighting Devices and Components".) Immediately after the preceding test has been completed, there shall be no evidence of sufficient corrosion to affect the proper functioning of the device or to soil hands or clothing.

3.5 *Fasteners*—3.5.1 *Standard.* All fasteners required for the assembly and complete installation of an adaptive control system in a particular *model* passenger automobile shall be provided by the manufacturer. Fasteners shall be designed or treated for resistance to vibration.

3.5.2 *Specification.* All fasteners of an assembled hand control system shall remain tightened securely within a 15% preload torque drop under vibratory motion producing a 4.6 g load (2.54 mm displacement at 30 Hz, i.e., $\pm$1.27mm from zero reference) in the axial and transverse direction of assembly.

3.5.3 *Test 5.* Resistance to vibration shall be tested in the laboratory by vibrating of the fully assembled control system, including all installation hardware. A vibratory force causing 2.54mm displacement ($\pm$1.27mm from zero reference) at 30 Hz shall be applied in the axial and transverse direction of the assembly for 30 minutes each. Locking torques of all fasteners shall be measured prior to testing, and changes in pre-load values shall be recorded after completion of the vibration test. The fasteners shall retain preload torques within a 15% allowable variation after testing.

3.6 *Electrical Components and Wiring*—3.6.1 *Standard.* All electrical components and wiring included on adaptive automotive control systems shall conform to applicable SAE Standards or SAE Recommended Practices, e.g., SAE J556 - Automobile Wiring.

3.6.2 *Specification.* Two-wire or single-wire systems shall be termed respectively "insulated-return" and "ground-return" systems. All electrical systems shall be designed and packaged to protect the driver against injury resulting from accidental shock, short-circuits, electrical fires, etc.

3.6.3 *Test 6.* Electrical components and wiring shall be considered integral parts of a control system, and shall be tested for fatigue resistance and resistance to vibration during the performance of (3.3.3.2), Test 2 (3.3.3.3), Test 3 and (3.5.3) Test 5. Any loosening of assembly hardware, or damage sustained by an electrical component during testing shall disqualify the entire system from acceptance.

3.7 *Safety*—3.7.1 *Sharp Edges and Projections*—3.7.1.1 *Standard and Specification.* All adaptive automotive control systems shall be free of sharp edges and jagged projections to minimize injuries and damage to clothing of both handicapped and non-handicapped drivers (FMVSS 201).

3.7.1.2 *Test 7.* All fully assembled systems shall be visually inspected in a laboratory set-up (simulator). All hazardous features shall be a cause for rejection of a device.

3.7.2 *Conventional Use of Motor Vehicle*—3.7.2.1 *Standard.* All adaptive control devices shall be designed to permit the conventional use of the standard automotive controls by non-handicapped drivers.

3.7.2.2 *Specification.* Brake and accelerator pedals shall remain unobstructed after adaptive controls have been properly installed according to the manufacturer's instructions.

3.7.2.3 *Test 8.* Acceptability of a particular design shall be verified by observation in the laboratory, where it shall be clearly demonstrated that brake and accelerator connecting hardware shall not obstruct control pedals used by drivers in the normal mode.

3.7.3 *Neutral Position of Control System*—3.7.3.1 *Standard and Specification.* Hand control systems shall be balanced so that neither the brake nor the accelerator are actuated in the hands-off mode (FMVSS 124).

3.7.3.2 *Test 9.* Acceptability of a particular device shall be verified in the laboratory by means of a simulated automotive installation.

3.8. *Mode of Operation*—3.8.1 *Acceleration and Brake Motion*—3.8.1.1 *Standard and Specification.* Adaptive hand control systems shall be designed to require distinctly different motions for acceleration and brake actuation.

3.8.1.2 *Test 10.* Functional adequacy shall be verified by observation in the laboratory where it shall be evident that distinctly different motions for actuation of the accelerator and brake pedals are provided.

3.8.2 *Restriction of Accelerator Motion for Mechanically Linked Hand Controls*—3.8.2.1 *Standard and Specification.* Adaptive hand control systems shall not permit actuation of the accelerator by forward inertial movement of the driver.

3.8.2.2 *Test 11.* Acceptability of an adaptive automotive hand control system shall be verified by observation in the laboratory, where it shall be evident that the accelerator cannot be actuated by a forward push away from the driver.

4.0 *Installation of Adaptive Equipment to Passenger Automobiles*—4.1 *Method of Attachment*—4.1.1 *Standard.* Manufacturers shall specify the appropriate method of installation for each type of automobile for which his device is designed.

4.1.2 *Specification.* A brochure containing written and graphic instructions for installing each control system shall be provided by the manufacturer *for each type, year and make of automobile for which his product is intended.*

4.2 *Certified Installation.* Upon completion, the installation must be certified as complete and safe. The VA strongly urges that installation be accomplished by highly experienced auto mechanics who have familiarized themselves with these devices.

4.3 *Safety Features of the Automotive Steering Column.* Installation of an adaptive hand

control system shall not interfere with the collapsibility of the steering column or any other safety features of the automobile. The collapse of a steering column in the event of a collision shall not expose the driver to hardware normally behind the steering wheel. In such cases, it is assumed that the driver impacts with the steering wheel (FMVSS 203).

4.4 *Alterations of the Passenger Vehicle.* The use of adaptive equipment shall not result in alterations of the passenger automobile which impair or reduce other safety features. Although it is desirable not to deface the interior, this desire is of secondary importance to assuring the secure attachment of all devices.

4.5 *Installation Instructions.* Complete installation instructions shall be packaged with each adaptive automotive control device (4.1), including a parts list of components. The instructions shall be clear and free of ambiguity, and shall be supplemented by photos and illustrations to facilitate the installation of the device. The manufacturer's concern for proper installation shall be clearly stated. A source of assistance and/or information (phone number and address) shall be provided.

4.6 *Use Instructions.* Complete instructions on the operation and use of the driving controls shall be packaged with each driving aid. These instructions shall be supplemented by photos and illustrations as needed. Suitable caution on gaining familiarity with a new driving method shall be given prominence.

5.0 *Sampling and Inspection by the Manufacturer*—5.1 *Sampling.* Samples of adaptive automotive driving aids shall be submitted before the end of November of each year to be tested for contract qualifications. These samples shall be compatible with passenger-type motor vehicles listed by the manufacturer of adaptive equipment for the calendar year ahead. They may be designed for use exclusively on vehicles with power brakes or for vehicles without power brakes; the manufacturer must clearly specify that they can be used for manual (non-power) braking. The manufacturer shall supply the VA Prosthetics Center, 252 Seventh Avenue, New York, N.Y. 10001 with one (1) complete production sample of each device submitted for compliance testing, free of charge. These samples will not be returned to the manufacturer, nor will they be issued to handicapped drivers. Samples submitted for testing before the end of November which fail to qualify may be resubmitted after appropriate modifications for retesting within 90 days of the initial submission date. The VA Prosthetics Center will at times purchase production samples for additional testing, as required.

5.2 *Inspection by the Manufacturer.* In view of the implied seriousness of in-service failures, quality control inspections made by the manufacturer shall be 100% on every part packaged and commercially sold. Evidence of quality assurance shall be included with every item sold, and can be in the form of a seal, inspection stamp, tag, or any other legible identification. The responsibility of product liability rests with the manufacturer of every adaptive device. Uninspected items shall be returned to the manufacturer.

5.2.1 *Identification Marking.* All adaptive devices shall bear a serial number and the name and address of the manufacturer. This may be engraved or placed on a permanently affixed tag which will remain visible after installation of the components.

5.2.2 *Warranty.* A statement of warranty shall be packaged with each adaptive device, assuring the quality of materials and workmanship of the product for at least one year from the date of installation. The warranty shall state that if defects are found during the warranty period, the device will be replaced or a refund made by the seller.

5.2.3 *Claims Made.* Advertising literature shall reveal the adaptive equipment manufacturer's name and address. All claims of approval by private groups, local, state or federal government shall be specific as to the approving agency and the acceptance test protocol. Such claims shall be documentable on request. Furthermore, all claims of scientific merit shall be clearly stated and documentable on request.

5.2.4 *Other Literature.* All promotional and technical literature shall clearly describe the

types of driving aids available and the types of disabilities they were designed to service.

6.0 *Distributors of Adaptive Automotive Control Equipment.* A distributor of adaptive automotive driving aids is subject to the same standard as the manufacturer with regard to claim of approval or scientific merit (see standard 5.2.3). All literature on driving aids furnished by the seller shall contain the seller's name and address.

7.0 *Test Procedure.*—7.1 *Static Testing (Test 1).* Static testing shall be conducted by applying either a force of 62.5 lbs. (278 newtons) for hand controls used for power brakes, or a force of 150 lbs. (667.2 newtons) for hand controls used for manual (non-power) brakes, to the handle of the control lever. The force shall be directed to simulate brake actuation of the fully assembled adaptive control system. The test sample is mounted on a laboratory simulator and positioned within the test space of the test machine load frame (INSTRON or equivalent). The readout and recording instrumentation of the test machine shall indicate that the 62.5 lb. (278 newtons) force, or the 150 lb. (667.2 newtons) force is being applied for a period of 30 to 35 seconds. Changes in alignment, loosening of parts, or permanent deformations indicate failure of the complete system.

7.2 *Fatigue Life Cycling (Test 2).* Cycling is accomplished using a combination axial and torsional testing machine (INSTRON or equivalent). The testing machine is programed to control a force of 50 lbs. (222.4 newtons) or a force of 120 lbs. (533.8 newtons) delivered by a hydraulic actuator to the handle of the Control Lever of a completely assembled adaptive automotive hand control system. The particular hand control system is fully assembled on a Laboratory Simulator and positioned within the test space of the test machine load frame. The readout and recording instrumentation of the test machine verifies that the required test load is applied to simulate either brake or accelerator actuation within 0.5 to 1.0 seconds per cycle. Since the required motions for actuation of adaptive automotive brake and accelerator controls vary considerably for particular hand controls, the cyclic test machine shall be programed to provide linear and rotary motion as needed. The test machine is biaxial, and therefore capable of applying and controlling axial and torsional loads simultaneously. A fatigue life cyclic test of 250,000 machine cycles shall be completed, applying mutually exclusive motions for acceleration and brake actuation. The cyclic program is monitored throughout the test with periodic inspection of test samples at intervals of 50,000 cycles, to either assure that satisfactory progress of fatigue life cycling is being made, or discontinue further testing.

7.3 *Resistance to Vibration (Tests 3, 5, and 6).* Resistance to vibration testing shall be conducted on individual components (under Test 3) or on the completely assembled adaptive automotive control system (Tests 5 and 6) installed in a laboratory simulator. The laboratory simulator, including the particular adaptive device, is mounted on a vibration testing machine for testing in the axial as well as transverse direction of component assembly. The vibration testing machine is set up to produce a 2.54 mm displacement ($\pm$1.27mm from zero reference) at 30 Hz, resulting in an approximate 4.6 g load. All fasteners, wiring and hardware including resistance-to-vibration type coatings, etc., shall be included in simulating an installation of the particular device in a passenger automobile.

7.4 *Laboratory Simulator.* The laboratory simulator is a mechanical test jig that permits simulated set-up of a variety of adaptive automotive driving aids submitted to the VA Prosthetics Center, New York, N.Y., for evaluation or compliance testing. Essentially, the laboratory simulator includes a standard automotive steering wheel, accelerator pedal, brake pedal, as well as a rigid non-automotive steering column attached to part of a simulated fire wall. The jig shall be used to carry out Fatigue Life Testing (3.3.3.2 Test 2), Resistance to Corrosion Testing (3.4.2 Test 4), Resistance to Vibration Testing (3.5.3 Test 5), Testing of Electrical Components and Wiring (3.6.3 Test 6), as well as all other compliance tests depending on visual inspection of an assembly or mode of operation of the particular adaptive automotive system.

b. *Adaptive Automotive Equipment Manufacturers in Compliance with VA Document VAPC-A-7505-8.* Following is a list of adaptive automotive equipment manufacturers who have complied with VA requirements:

Blatnik Precision Controls, Inc.
1523 Cota Avenue
Long Beach, California 90813
(213) 436-3275

Drive-Master Corp.[a]
61 North Mountain Avenue
Montclair, New Jersey
(201) 744-1998

Ferguson Auto Service[b]
1112 North Sheppard Street
Richmond, Virginia 23230
(804) 358-0800

Gresham Driving Aids[c]
P.O. Box 405
Wixom, Michigan 48096
(313) 624-1533

Handicaps, Inc.[d]
4345 South Santa Fe Drive
Englewood, Colorado 80110
(303) 781-2062

Hughes Hand Driving Controls, Inc.
Box 275
Lexington, Missouri 64067
(816) 259-3681

Kroepke Kontrols, Inc.
104 Hawkins Street
Bronx, New York 10464
(212) 885-1547

Manufacturing & Production Services
4666 Mercury Street
San Diego, California 92111
(714) 292-1423

Mross Inc.
Star Route Box 42
Elizabeth, Colorado 80107
(303) 646-4096

Nelson Products
5690-A Sarah Avenue
Sarasota, Florida 33577
(813) 924-2058

Smith's Hand Control
1472 Brookhaven Drive
Southaven, Mississippi 38671
(901) 743-5959

Thompson Hand Control[e]
4333 N.W. 30th Street
Oklahoma City, Oklahoma 73112
(405) 946-9517

Trujillo Industries
5726 W. Washington Blvd.
Los Angeles, California 90016
(213) 933-7469 (manufactures steering assists only)

Wells-Engberg Co.[f]
P.O. Box 6388
Rockford, Illinois 61125
(815) 874-6400

Wright-Way Inc.
P.O. Box 907
Garland, Texas 75040
(214) 278-2676

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[a] Modified after Sept. 1, 1975.
[b] Modified after Sept. 1, 1975.
[c] Modified after June 1, 1975.
[d] Modified after Sept. 1, 1975.
[e] Modified after Sept. 1, 1975.
[f] Manufactured after March 1, 1976 with S.N. 10,003 and up.

c. *Development of Standards for Van Wheelchair Lifts.* The first stage in developing a "VA STANDARD DESIGN AND TEST CRITERIA FOR SAFETY AND QUALITY OF POWERED AUTOMOTIVE WHEELCHAIR LIFTS FOR PASSENGER MOTOR VEHICLES" requires that there be a detailed engineering analysis of design, test, and performance data resulting from evaluations of a wide variety of commercially available wheelchair lift systems. In conformance with these requirements, a VA-sponsored evaluation of rear- and side-door van wheelchair lifts is now in progress at Texas A&M University. It is intended to provide the parameters for the standard. The criteria used for this evaluation are as follows:

1. The extent to which the lift can be installed and operated according to the manufacturer's instructions and claims;
2. Its adherence to accepted engineering design and shop fabrication practices;
3. The lift system's safety features and shortcomings;
4. A determination of potential user errors in using the lift and the possible results of these errors;
5. The ease and convenience of using the lift by handicapped persons who possess various capabilities.

Upon completing the physical testing associated with the various lift systems (from as many as 20 or more participating manufacturers), a first draft of a tentative VA standard will be available for discussion among representatives of the automotive wheelchair lift industry, handicapped consumer groups, and the Veterans Administration.

In a manner similar to that which led to the development of VA Standard VAPC-A-7505-8, the current standard for adaptive automotive systems, this effort is expected in the near future to result in a workable and much needed standard for automotive wheelchair lifts for handicapped drivers.

d. *Van Wheelchair Lift Manufacturers and Van Modifiers.* Following is a list of recognized van wheelchair lift manufacturers and/or van modifiers:

Amcraft Corp.
1059 McCue Avenue
San Carlos, California 94070
(415) 592-7527

Braun Corporation
1014 South Monticello
Winamac, Indiana 46996
(212) 946-3647

Casady Safety Van Lift
1627 Linnea Avenue
Eugene, Oregon 97401
(503) 686-9706

Collins Industries, Inc.
P.O. Box 58
Hutchinson, Kansas 67501

Compass Industries, Inc.
715 Fifteenth Street
Hermosa Beach, California 90254
(213) 379-3470

Double D Industries
110 Fox Hill Rd.
St. Charles, Missouri 63301
(314) 946-7860

Drive-Master Corp.
61 North Mountain Avenue
Montclair, New Jersey 07042
(201) 744-1998

Helper Industries, Inc.
832 N.W. 1st Street
Fort Lauderdale, Florida 33310
(305) 524-7231

Maxon Industries, Inc.
1960 East Slauson Avenue
Huntington Park, California 90255
(213) 589-7321

Motorette Corporation
6014 Reseda Blvd.
Tarzana, California 91356
(213) 345-6490

Para Industries, Ltd.
#6-4826 11th Street, N.E.
Calgary, Alberta, Canada
(403) 276-3133

Ricon Corporation
15806 Arminta Street
Van Nuys, California 91406
(213) 994-7722

Robin-Aids, Inc.
3353 Broadway
Vallejo, California 94590
(707) 643-1785

Royce International
4345 S. Santa Fe Drive
Englewood, Colorado 80110
(303) 789-1032

Mobility Engineering and
Development, Inc.
15936 Blythe Street
Van Nuys, California 91406
(213) 785-0958

Sevier Manufacturing Co.
229 Prince Street
Sevierville, Tenn. 37862
(213) 923-4296

Speedy Wagon Sales Corp.
2237 Harvester Road
St. Charles, Missouri 63301
(314) 447-5145

Target Industries
P.O. Box 3898
8 Heywood Street
Springfield, Mass. 01101
(413) 736-5442

II. TESTING

A. Testing

1. *Lower-Limb Torque Absorbers*

Short term testing has continued (refer to the Fall 1975 Bulletin, BPR 10-24) on the four torque-absorption units developed by Weber-Watkins, Hosmer-Dorrance, U.S. Manufacturing, and UC-BL.

Static tests to determine torque versus angular deflection, with and without an axial load, have been completed. The U.S. Manufacturing Company's Star Rotator has been subjected to a bending moment of 80 lbft (108.5N-m) applied sinusoidally in the sagittal plane. There was no measurable permanent deformation in the unit after 150,000 cycles. Each of the remaining units will be cycled in a similar fashion when a test fixture is modified to accept them.

2. *Test Standards for Wheelchair Cushions*

The equipment required for the testing phase of this program, with the exception of additional interface pressure transducers, has been purchased. Dr. George Van B. Cochran reports that the modified test apparatus, which will be used for laboratory testing of cushions, has been completed in the Helen Hayes Hospital, West Haverstraw, N.Y., machine shop. These tests, as well as the clinical tests, will be underway in March of 1976.

B. Compliance Testing

1. *Upper-Limb Components*

Hosmer-Dorrance, Inc., submitted an Army Prosthetic Research Laboratory Voluntary Closing Hook for annual compliance testing. This terminal device complied with the "Tentative Standards for Hook, Mechanical, Voluntary Closing, for Upper Extremity Amputees" APRL specification.

2. *SACH Feet*

A unique SACH foot (Fig. 32) has been submitted for cyclic testing by the developer, Mr. Michael W. Ryan of Vallejo, California. The keel of the foot is designed to allow limited plantar flexion and dorsiflexion, inversion and eversion, and transverse rotation of the ankle, qualifying the foot for a Class III rating. As shown in Figure 32, this is accomplished by means of a heavy coil spring A welded to a shank attachment plate B, and a short sole plate C. The distal end of the sole plate is stiffened with a ball-jointed tie rod D. Toe belting E is riveted to the sole plate.

The tests are intended to aid in the development and refinement of the design. Thus far four samples have been tested. Each successive foot has been more durable than its predecessor, but they do not as yet comply with the durability requirements of VAPC specifications.

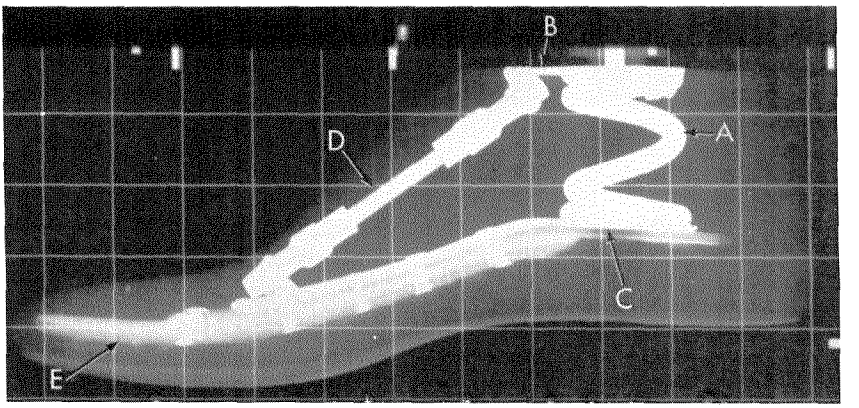

FIGURE 32. — X-Ray of internal structure of Ryan SACH Foot.

3. *Wheelchairs*

At the request of the Division of Vocational Rehabilitation, State Board of Vocational Education of West Virginia, VAPC has agreed to evaluate and test samples of wheelchairs which are being considered for contract on a West Virginia statewide basis.

Thus far, one sample has been received, an Everest and Jennings Model P8AU250-770, which has been tested and found to comply with current VAPC standards.

4. *Stump Socks*

a. *Shrink Resistant Woolen Stump Socks.* Samples of shrink-resistant woolen stump socks have been submitted for evaluation and testing. The chemical process is being developed jointly by the Navy Prosthetics Research Laboratory, Oakland, California, and the Western Regional Research Laboratory, Agricultural Research Service, Department of Agriculture, Berkeley, California. Preliminary results are highly satisfactory.

Additional samples have been supplied and are now undergoing long-term testing to determine the durability of the process. These tests include machine drying (tumbler), a practice normally advised against by manufacturers.

Concurrently, NPRL and WRRL are conducting a pilot wearer-study (25 subjects).

b. *Woolen and Cotton Stump Socks.* At the request of the VA Marketing Center, Hines, Illinois, samples of the Comfort stump socks (woolen) manufactured by the John D. McCann Co., Burlington, New Jersey, and the Knit-Rite stump sock (cotton) manufactured by the Knit-Rite Co., Kansas City, Missouri, were tested for compliance with current VA specifications. The samples passed all of the requisite tests and inspections.

III. CLINICAL EVALUATION

A. Patient Profiles

As previously described in the Fall 1975 Bulletin (BPR 10-24), the VA Prosthetics Center Clinic Team is composed of highly qualified individuals with many years of experience in prosthetics, orthotics, physical therapy, and orthopedics. Proximity to several outstanding hospitals and an outpatient clinic provides the opportunity for consultations on short notice with dermatologists, neurologists, psychologists, psychiatrists, social workers, and other specialists.

Over the 6-month period of July 1, 1975, to December 31, 1975, 117 separate clinics were conducted by the Clinic Team; some 651 eligible veterans were interviewed, observed, evaluated, and treated. This represents a fairly typical case load of VAPC clinical operations. While other large outpatient treatment facilities may handle similar numbers, at the VAPC we see an extremely broad variety of amputees, paralytics, and multiple-injury patients, some with unusual problems that may be rarely seen outside of our clinics. The characteristic profile of this large and varied group varies from time to time within broad limits. These variations are greatly influenced by the development of new devices and improved techniques and procedures.

The numbers and types of patients treated in our clinics during this report period are shown in Table 1, together with descriptions of their disabilities.

It should be remembered that these are veteran patients and not "typical" of the general population. Our statistics are therefore not readily comparable, for example, to a sampling of an equal number of civilian amputees. Most civilian amputations are necessitated by vascular insufficiency of the limbs of geriatric or near-geriatric patients, and by far the great majority of amputations (80 to 90 percent) are at below-knee levels. Shell fragments and bullets leave the military surgeon little choice regarding amputation level, and a thigh is a much larger target than a leg. Consequently, 60 percent of our patients are above-knee amputees and 40 percent are below-knee amputees.

Many of our amputees, because of the mode of injury, have neither stumps of ideal length nor electively contoured stumps, and because of commendable surgical attempts to retain a below-knee stump, most have multiple scars, and, on occasion, a mosaic of skin grafts. These present fitting problems which our prosthetic staff has learned to deal with satisfactorily.

Since these statistics apply primarily to war-wounded patients, they should be viewed in that manner. In future issues of the Bulletin, more definitive analyses of our case load wil be presented in greater detail.

TABLE 1

Amputation

Area of involvement	Specific level of involvement	Number of patients
Lower limb unilateral	Above Knee	168
	Below Knee	111
	Transmalleolar (Syme's)	19
	Hip (Disarticulation)	16
	Mediotarsal (Chopart)	3
Lower limb bilateral	Below Knee	19
	Above Knee	15
	Above Knee/Below Knee	6
	Below Knee/Partial Foot	1
	Above Knee/Transmalleolar (Syme's	1
Upper limb unilateral	Below Elbow	10
	Above Elbow	5
Upper limb bilateral	Above Elbow	1
Triple	Above Knee/Below Knee/Below Elbow	2
		(377 total)

Nuromuscular or Skeletal Impairment

Area of involvement	Specific level of involvement	Number of patients
Lower limb unilateral	Ankle-foot	138
	Foot	53
	Knee-Ankle-Foot	14
	Knee	2
Lower limb bilateral	Ankle-Foot	8
	Knee-Ankle-Foot	5
Upper limb unilateral	Arm-Elbow-Forearm; Wrist-Hand	22
	Serratus Anterior	1
Trunk	Lumbosacral Spine	20
Miscellany	Varied (Wheelchairs, etc.)	6
		(269 total)

Amputation and
Neuromuscular or Skeletal Impairment

Area of involvement	Specific level of involvement	Number of patients
Lower limb bilateral	Below Knee/Ankle-foot	5
		(5 total)

B. Special Case Histories

The Clinic Team's policy is to provide the most up-to-date service with the least inconvenience for the eligible veteran. This service may be in the

form of "customization," i.e., a particular patient may be treated for a unique problem. Or it may entail a long-term progression of fitting adaptive devices: for example, a patient may progress from a bulky, uncomfortable prosthesis which limits his mobility, to, eventually, a lightweight and comfortable prosthesis that provides far greater mobility. In either category we are regularly faced with challenging treatment problems. Two such cases are described in the following paragraphs.

The case of a Korean War veteran is an example of a "customization" approach. This veteran sustained multiple shell-fragment wounds of the left leg in 1950. He subsequently developed osteomyelitis, which was secondary to a compound fracture of the left distal femur (Fig. 33). At present the patient continues to have drainage from the osteomyelitic lesion. Motion of the left knee is from 5 to 25 degrees with moderate lateral instability.

Because of this knee condition, the consensus reached by the Clinic Team was that the patient would require knee bracing but that it would be possible to avoid extending the brace to the shoe. The brace presently worn by the patient is not the unweighting type. It is a conventional solid knee KAFO (knee-ankle-foot-orthosis) (Fig. 34). This brace has been worn by the patient with continuous stress at the fracture site, the result

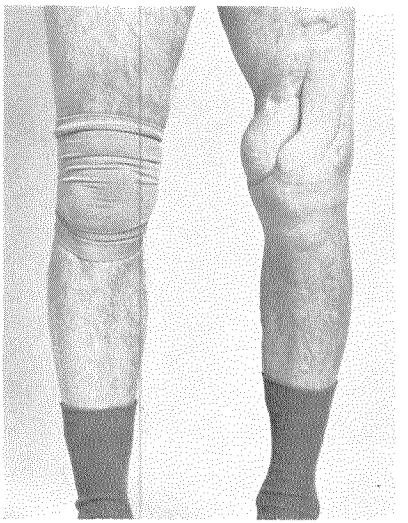

FIGURE 33.—Patient with ostemyelitic lesion of the left femur.

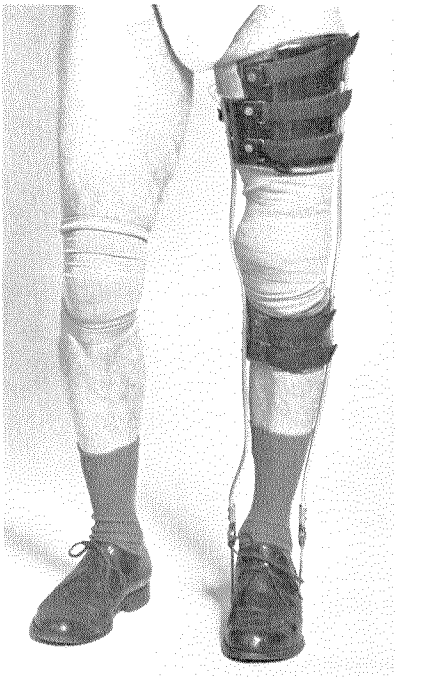

FIGURE 34.—Patient with a conventional solid knee KAFO (knee-ankle-foot orthosis).

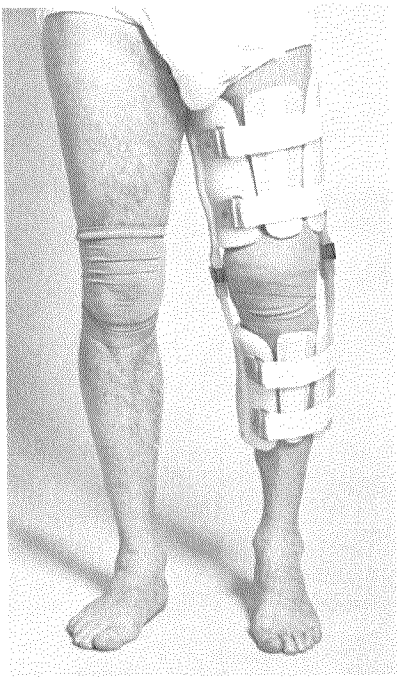

FIGURE 35.—Patient with polypropylene knee orthosis.

of which has been to produce additional bone formation. A severe depression in the patient's distal thigh had been previously built up with full-thickness skin grafts but some depression nevertheless still remains. This depressed area can now be utilized to prevent distal slippage of a polypropylene knee orthosis (Fig. 35), thereby making a PTB (patellar tendon bearing) strap unnecessary. The polypropylene knee orthosis is lighter in weight than the solid knee KAFO, is much more comfortable, and allows for flexion on sitting.

It was therefore decided by the Clinic Team to supply the patient with a well-padded polypropylene left-knee orthosis. The thigh segment and padding of the polypropylene left-knee orthosis, according to the prescription, should be contoured to fit into the pertinent area of the distal femur above the knee, for the purpose of preventing distal slippage of the orthosis.

An example of a long-term approach is the case of a World War II veteran who suffered a land-mine injury that resulted in the amputation of his left leg below the knee.

In July of 1970 a below-knee prosthesis with a *gluteal-bearing* corset, side bars, and an open-end plastic socket with soft insert was prescribed. There is evidence of multiple areas of scarring in the popliteal area and over the head of the fibula, and in areas anterior to these.

In January of 1974 a below-knee prosthesis with a *long thigh corset* and a Greissinger foot was prescribed. The Greissinger foot was prescribed

because of the patient's tendency to walk on the lateral border of the foot, and because the geographical area in which he resides is composed of somewhat irregular ground. The patient likes the action of the Greissinger foot.

Progression from a bulkier and more limiting prosthesis to one that was lighter and less limiting allowed the patient to rely to a lesser degree on the prosthesis and to an increasingly greater degree on his own muscles. As a result, in April of 1975, the patient's left thigh was strong enough for him to be prescribed a *PTB prosthesis*. A PTB prosthesis comprising a soft socket insert, cuff suspension, and a Greissinger foot (Fig. 36) was therefore prescribed by the Clinic Team. At this time the patient is quite content with his PTB prosthesis. His left thigh has developed further, and he is able to walk greater distances with relative ease and comfort.

FIGURE 36. — Patient with PTB prosthesis and Greissinger Foot.