BIOENGINEERING EVALUATION AND FIELD TEST OF THE STAND-ALONE THERAPEUTIC AID

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INTRODUCTION

Early in 1963, laboratory evaluations of the Stand-Alone Therapeutic Aid were conducted by the Bioengineering Laboratory, the Testing and Development Laboratory, and the Limb and Brace Section—all sections of the VA Prosthetics Center in New York, N.Y. Findings based upon evaluations of two early models were made known to a representative of the manufacturer, Corporation for Medical Engineering, 8472 East Garvey Avenue, South San Gabriel, Calif.

A newer model (Model FVA 2100) was submitted by the manufacturer for laboratory evaluation. In May 1963, five additional devices of this design were obtained for use in a field test to be administered by the Research and Development Division of the Prosthetic and Sensory Aids Service, located in New York, N.Y.

Five Veterans Administration hospitals having Spinal Cord Injury Services were selected for participation in the field test. We are grateful to the personnel who cooperated in the study at the following hospitals: VAH, Hines, Ill.; VAH, West Roxbury, Mass.; VAH, Long Beach, Calif.; VAH, Memphis, Tenn.; and VAH, Richmond, Va.

The cooperation of the Area Medical Offices in Atlanta, Ga., Boston, Mass., Columbus, Ohio, San Francisco, Calif., and Trenton, N.J., is also acknowledged.

The independent experience which the Brooklyn Outpatient Clinic had with one patient using the device for approximately a 10-month period was also utilized in our study, and it too is covered in this report. In addition, the report includes data provided by the VA Hospital in Coral Gables,

Fla., covering the use by one subject of the Stand-Alone for a 3-month period.

Also appreciated were the efforts of Mr. Earl A. Lewis of the Research and Development Division, PSAS, in the conduct of the study and the writing of the report.

BIOENGINEERING EVALUATION OF STAND-ALONE THERAPEUTIC AID

Description

The Stand-Alone is a device designed for the use of paraplegic and incomplete quadriplegic patients for whom standing erect is of therapeutic value. It purports to offer them a relatively wide range of mobility while they stand, thus permitting them to carry on part of their normal activity, which might otherwise be curtailed if they were to stand in bars or with braces and crutches. The Stand-Alone may be considered a mobile, portable, collapsible set of standing bars (Fig. 1).

An earlier version of the model was initially submitted for evaluation. A mechanical analysis at that time brought out the following problems:

1. An extension of the frame designed to prevent tipping made it impossible to climb or descend a curb. It was also difficult to roll over a door threshold for the same reason.
2. There was a possibility of getting clothing caught in the exposed sprockets, locking handle, and hub nuts.
3. Locking handles interfered with the spokes of the handwheels when the locks were released.
4. It was difficult to insert the detent pins on the back crossbar assembly and to extract the pins when under load. The detent pins were too tightly fitted to the holes which received them.
5. It was difficult for the occupant to remove and detach seat.
6. The operating manual required further clarification.

The device was resubmitted in a substantially improved form: clothing guards were installed over the sprocket; locking handles were housed to prevent jamming between spokes; pins were made slightly undersized to improve the ease of insertion; and latches were installed on the anterior and posterior crossbar assemblies to prevent inadvertent lifting of abdominal and back supports. Rearward projections were eliminated. No change was made in the method of attaching and detaching the seat.

Evaluation Program: Procedures and Findings

The most recent model (FVA 2100) was evaluated in a program which included:

1. Mechanical analysis of design and materials, mechanical linkages, and dimensions.
2. A review and analysis of modes of transfer to and from wheelchairs.

3. Evaluation of maneuverability in turning, backing up, ascent and descent of slopes, obstacle clearance, bathrooms, and use on such surfaces as rugs, dirt, concrete, and grass.

4. Analysis of the range of useful motion as regards extent of arm reach while standing in the device.

5. Assessment of stability on level ground and on inclines.

6. Measurement of the force requirements to start and drive the Stand-Alone, the frictional characteristics of the system, and the energy cost of the typical use pattern.

7. Tabulation of subjective reactions of patients, e.g., their opinions on the advantages and disadvantages of specific features.

Mechanical Analysis of the Design and Materials

Two side frames made of 7/8-in. (O.D.) chrome-plated tubular steel form the basic structure of this unit. Mounted on the anterior section of each frame half is an 8-in.-diameter free-rotating wheel with rubber tire, whereas the posterior area of each frame half houses a deep-treaded rubber wheel and sprocket. These two frame halves join at the kneepan assembly and are designed to constitute a collapsible unit for compactness in shipping or storage.

A plastic-coated handwheel assembly, 19 in. in diameter, is located on each side of the frame, the center of rotation being approximately 31 in. from the floor. Within the assembly of each handwheel is a sprocket, which transmits torque forces exerted through a chain to the lower sprocket and rear wheel. By manipulation of the two handwheels, the patient controls

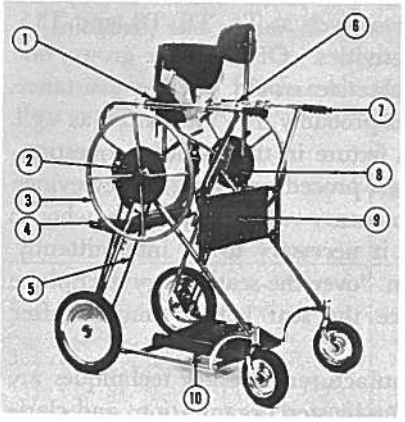

FIGURE 1. Stand-Alone components: (1) back crossbar assembly; (2) brake assembly; (3) handwheel; (4) seat; (5) chain assembly; (6) chest crossbar assembly; (7) handgrip; (8) guard; (9) kneepan assembly; and (10) floor pan.

motion and direction. A positive-type locking device is installed on the inner side of each handwheel.

Attached to the frame are a chest-rest assembly, lower backrest assembly, and the upper backrest assembly. Anterior-posterior adjustments are provided by detent pins and a series of holes in the upper rail. The chest and backrest assemblies can be raised and lowered to suitable heights easily.

The measurements of the Stand-Alone are: overall width (open), 25½ in.; overall width (folded), 14 in.; overall length, 40 in.; overall height (floor to horizontal upper rail), 41½ in.; weight (including accessories), 79 lb.; and inside width (open), 15 in.

The Stand-Alone Therapeutic Aid seems to be well made and free from any defects that would affect its appearance or serviceability. Components and assemblies appear sound in design and adequate in strength for the intended use. When folding this unit, the attendant must be familiar with certain operational procedures, as outlined in an instruction manual supplied by the maufacturer.

Subjects Participating in Laboratory Tests

Five paraplegic veterans volunteered their services in the laboratory testing program: E.R., a 33-year-old male with a traumatic transverse myelopathy at T4 level; E.B., a 35-year-old male with a traumatic transverse myelopathy at T6 level; D.W., a 50-year-old male with a traumatic transverse myelopathy at T8 level; A.B., a 34-year-old male with a traumatic transverse myelopathy at T11 level; J.G., a 33-year-old male with a traumatic cauda equina syndrome.

Mode of Transfer

Transfer to and from the Stand-Alone to a wheelchair, a chair, and a bed was accomplished without assistance by one subject with a cauda equina lesion. The other four subjects, with lesion levels at T4, T6, T8, and T11, required some degree of help for these activities. Of the latter group, one subject (T11) stated that additional practice would obviate assistance. Laboratory observers agreed that this was probably true for the T8 as well.

The utility of the seat as a permanent fixture in this device is questionable; the subjects did not sit during the test procedures nor did they evince a desire to do so. It may have some temporary value for patients who, in becoming accustomed to standing, feel it necessary to sit intermittently. In addition, use of the seat requires an "over-the-seat" entry technique because the patient is unable to replace the seat behind himself after standing erect.

The instructions provided by the manufacturer on entry techniques are not adequate. They need more detail, step-by-step organization, and clarification of language.

Maneuverability and Mobility

All five subjects were able to propel the Stand-Alone without difficulty over thresholds and through doorways not much wider than the Stand-Alone on such varying surfaces as tiled corridors and concrete. In the current configuration, obstacles up to 2½ in. high were cleared.

Range of Useful Motion and Activities

All five subjects demonstrated their ability to carry out a variety of practical activities while in the Stand-Alone. Included were opening and closing of doors, shaving and washing, drawing a glass of water from the sink, eating, using an oven and a stove, placing and retrieving objects from a table, turning lights on and off, using a wall telephone, reaching objects on a 7-foot-high cupboard shelf, washing dishes, and opening and removing objects from a refrigerator.

Erect in the Stand-Alone, all of the subjects naturally could reach higher than they could sitting in their wheelchairs; the Stand-Alone offered no restrictions to arm movement above the head or at shoulder height; however, none of the subjects could reach objects that were placed on the floor (Table 1). The downward reach was related to the number and kinds of supporting accessories used, i.e., those subjects with high-level lesions who used the chest-rest assembly were more restricted, as was the one subject with a low-level lesion who also used the chest piece.

Stability

Properly supported in the Stand-Alone, a normal adult could not voluntarily tip or unbalance the device in any direction on a level surface. On inclines, however, stability in both the anterior-posterior (A–P) and medical-lateral (M–L) directions is limited.

Unloaded, the center of gravity (CG) projection of the Stand-Alone

TABLE 1.—*Maximum Downward Reach*

Subject	Lesion Level	Maximum Downward Reach (inches from floor)	
		Front	Side
1	T4	31	24
2	T6	12	18
3	T8	10	8
4	T11	8	8
5	Cauda equina	24	20

falls approximately 14 in. behind the front axle in the A–P plane; with a patient, it migrates approximately 2 in. farther forward (Fig. 2). In the M–L plane it falls equidistant between the wheels, i.e., 12 in. from either side. As the normal vertical position of the human CG is approximately 56 percent of the body height measured from the floor, the CG of a 70-in.-tall patient is found at approximately 40 in. above the floor (Fig. 3).

By calculation, the CG projection would fall beyond our base of support on a slope of approximately 17° in either the A–P or the M–L planes (Fig. 4); however, 17° cannot be considered the safe limit. Movement of torso or limbs will displace the CG, and instability may develop on slopes of less than 17°. On the basis of these data and the range of movement possible for the patient in the device, an 8°-slope would seem to be the maximum safe incline. With experience, the user might apply some adaptive techniques such as leaning forward going uphill and leaning backward going downhill in order to move along safely on steeper slopes, but it becomes difficult to maintain traction and to propel the Stand-Alone on slopes greater than 8°.

Energy and Force Requirements

Since the Stand-Alone is designed for paraplegics and quadriplegics, the forces required to propel the device were analyzed. Measurements were obtained of:

1. The forces required to start the Stand-Alone;
2. The energy cost of the typical use pattern;
3. The loss of input energy due to friction;
4. Cardiac responses.

Starting Forces. The forces required to set the Stand-Alone in motion were measured by pulling the Stand-Alone with a light cable, which was attached at the CG of the system, drawn over a pulley, and connected to a weight pan.

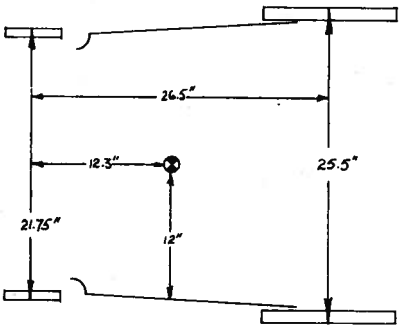

FIGURE 2. Center of gravity (CG) projections of Stand-Alone with patient. In the A–P plane, the CG projection falls approximately 12 in. behind the front axle, and in the M–L plane, it falls equidistant between the wheels.

The weight (in pounds) that first started the device, producing a continuous uniform movement of 1 foot, was recorded.

Under a load of 100 lb., the Stand-Alone required 2.97 lb. to start; with a load of 150 lb., a 3.72-lb. force was required. These forces are comparable to those for conventional and lightweight wheelchairs, i.e., between 3.0 and 3.5 lb. (1). Of more significance for patients of limited strength

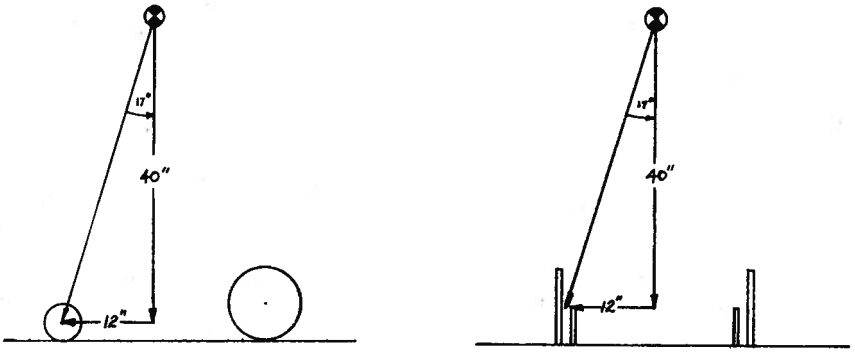

FIGURE 3. CG projection of patient erect in Stand-Alone (a) A–P plane and (b) M–L plane.

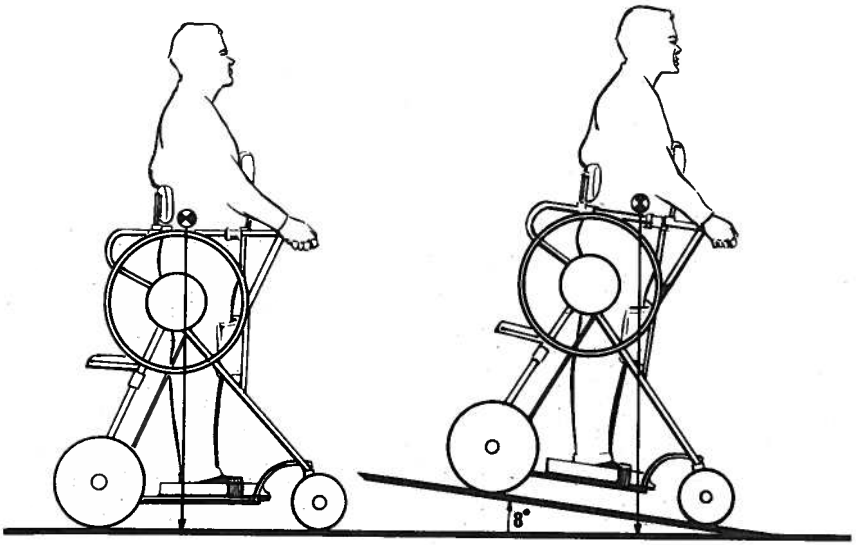

FIGURE 4. Shift of CG projection when Stand-Alone is on (a) level plane and on (b) 8° incline.

is the fact that only a 1.6-lb. force was required at the rim of the handwheel to start the Stand-Alone moving.

Energy Cost. Since many of the patients for whom this device is designed are limited in strength, and because the Stand-Alone weighs approximately 30 lb. more than a conventional wheelchair (75 lb. vs. 45 lb.) the effort involved in its use was of interest. In this connection, several kinds of energy were considered: the physiological effort or metabolic energy cost, the efficiency of use as indicated by the ratio of mechanical energy output in driving the device to the physiological energy input by the subject, and the energy loss due to friction.

The volunteer subject for this part of the study was a 32-year-old male paraplegic with a traumatic cauda equina. He was otherwise in good health and had no upper-extremity involvement. He was accustomed to the upright position as he periodically stood in long leg braces. In addition, his metabolic characteristics were well known to this laboratory since he had participated in several similar studies.

The energy cost of propulsion was calculated from measures of oxygen consumed during a standard performance with the Stand-Alone.* Each trial began with a pre-exercise rest period during which the subject's resting O_2 consumption rate was measured. The exercise consisted of starting the Stand-Alone from a stop, making four strokes, and gliding to a stop. This was repeated 20 times in two trials; in a third trial, a 3-stroke pattern was used (Fig. 5).

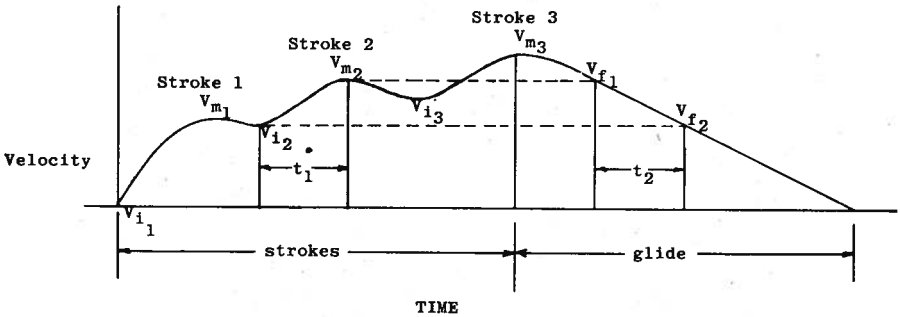

FIGURE 5. Analysis of energy transfer in a single stroke of the handwheel. V_{i_2} represents the velocity of the system at the beginning of the second stroke, and V_{m_2} represents the maximum velocity attained during that stroke. The energy lost to friction was calculated by determining the rate at which the velocity increase during the stroke was lost during the glide, when there was no energy input and the system was losing velocity at a rate determined by friction.

*In the open-circuit method used in this study, the subject breathed room air. All his expired air was metered and analyzed for CO_2, O_2, and N_2.

The net energy cost* of the activity was 0.065 Cal. per meter or 0.180 Cal. per stroke over the entire distance traveled at approximately 4.8 km. per hr. and at an average of 2.8 meters per stroke. Propelling a conventional wheelchair at a comparable velocity (4.7 km. per hr.) cost the same patient 0.023 Cal. per meter or 0.075 Cal. per stroke. The Stand-Alone, therefore, required approximately 2.8 times as much energy per meter traveled or 2.4 times as much energy per stroke.

In comparison to other modes of locomotion, an above-knee amputee walking at 3.9 km. per hr. uses 0.076 Cal. per meter; however, a normal person requires only 0.039 Cal. per meter to walk at approximately the same velocity.

The ratio of energy output to energy input is a useful index of efficiency. The mechanical energy output in using the Stand-Alone was determined by means of a tachograph, which provided a recording of the linear velocity of the device during use.

Mechanical Energy. Mechanical energy (E) was calculated by the formula:

$$E=\tfrac{1}{2}M_e\,(V_m{}^2-V_i{}^2)+\tfrac{1}{2}M_e\,(V_{f_m}{}^2-V_{f_i}{}^2)\,\frac{t_1}{t_2} \qquad (1)$$

where: M_e = Equivalent mass, i.e., the mass of the Stand-Alone and the man plus the inertial effects of the rotating components. It was assumed that the radius of gyration of the wheels was the outside radius.

V_m = Maximum velocity achieved during the stroke.

V_i = Initial velocity of the stroke.

V_{f_m} = V_m; it is projected on the glide pattern to determine t_2 (Fig. 5).

V_{f_i} = V_i; it is projected on the glide pattern to determine t_2 (Fig. 5).

$\frac{t_1}{t_2}$ = The ratio of energy input time per stroke to energy time for comparable loss in velocity during the glide.

As shown in Table 2, the useful energy, i.e., the kinetic energy plus the energy lost to friction (input) ranged from 7.957 to 8.387 kg.-m. per stroke for an average of 8.199 kg.-m. or 0.0192 Cal.

The efficiency of the apparatus was considered in terms of the ratio of energy lost to friction to the mechanical output energy. Friction in this connection relates to the sum of all the energy drains occurring at the tire-floor interface, within the tire material, and in all the wheel bearings

*Physiological cost values are expressed in net Calories, i.e., the excess energy consumed above the resting rate. (Calorie, kilocalorie, and great calorie are equivalent to 1,000 calories, gram calories, or small calories. In this paper, we use the term Calorie (capital C) for the great calorie.)

TABLE 2.—*Velocity, Energy Relationships* [a]

Stroke	Maximum Velocity per Stroke (km./hr)	Energy Input (kg.-m.)	Energy Lost Through Friction (kg.-m.)	Efficiency (percent)
1	4. 2	8. 387	1. 145	86
2	5. 1	8. 326	1. 844	78
3	5. 8	7. 957	1. 916	76
4	6. 3	8. 126	1. 820	77

[a] Averages of three trials at 20 cycles of 3 or 4 strokes each.

and axles. Energy loss due to friction was calculated from the second term of Equation (1):

$$\tfrac{1}{2} M_e (V_{f_m}{}^2 - V_{f_i}{}^2) \frac{t_1}{t_2} \qquad (2)$$

where t_1 is the stroke input time and t_2 is the time for an equal change in velocity during the glide (the period when only friction acts).

The frictional energy loss ranges between 14 and 23 percent of the mechanical energy per stroke, varying directly with velocity for the first three strokes; efficiency during the fourth stroke remained approximately the same as the third stroke.

At an average input energy cost of 0.164 Cal. per meter, and an energy output of 0.018 Cal. per meter, the patient operated the Stand-Alone at an efficiency of approximately 11 percent. There are no data, obtained under comparable conditions, with which to compare this efficiency figure; however, since Lehmann (2) has shown that human performance at intensity levels of 30 gram-calories per kilogram-meter and 20 gram-calories per kilogram-meter yield respectively efficiencies of 8 percent and 12 percent, an indirect comparison is possible. Converting the caloric cost per stroke obtained with the Stand-Alone (0.180 Cal. per stroke) to gram calories per kilogram-meter and dividing by the average energy input (8 kg.-m. per stroke) yields 22.5 gram calories per kilogram-meter. On Lehmann's table, this figure represents an efficiency of 11 percent.

Cardiac Responses. In terms of cardiac response to the Stand-Alone performance, the 4-stroke pattern raised the blood pressure from 10 to 14 units and raised the pulse rate 12 units above the pre-exercise rate. The 3-stroke pattern also raised both the blood pressure and the pulse rate, but only slightly. In all cases the pulse rate remained elevated following a 10-minute recovery period (Table 3).

TABLE 3.—*Cardiac Response to Stand-Alone Performance*

Stroke Pattern	Systolic Blood Pressure (Excess over resting)		Pulse Rate (Excess over resting)	
	Immediately after Exercise	After 10-min. Recovery	Immediately after Exercise	After 10-min. Recovery
4	14	0	12	12
4	10	10	12	12
3	2	−2	4	6

Subjective Reactions

All five subjects were very favorably impressed with the Stand-Alone. One subject stated that he preferred it to standing with braces. Because of the convenience of the Stand-Alone, he estimated that he would stand in it five or six times a day.

The subjects were asked to state their opinion as to the activities they thought they might be able to perform more conveniently with the Stand-Alone than with the wheelchair or with braces and crutches. Their responses included: playing ping pong, dishwashing, window cleaning, repairing, painting, and washing an automobile.

Few negative opinions were expressed: two subjects complained that the detent pins dug into their forearms when they pulled themselves into the Stand-Alone and again on getting out.

One subject who used the abdominal-support piece thought that the edge was too sharp. He also suggested the possible addition of armrests.

One subject felt that the seat was not padded sufficiently for a paraplegic to sit on for any length of time, nor did he think that it was wide enough for a high-level-lesion patient who had poor balance.

One subject tried the Stand-Alone at home for 1 week and used it to wash windows, to replace a light fixture, to clean his car, and to wash down kitchen walls. He experienced no problems propelling it on grass or on a gravel driveway. He had several occasions to use it on ramps, again with no particular problem.

Summary of Bioengineering Evaluation

In general, paraplegics with lesions below T8 will have little difficulty in developing the skill required to enter and leave the Stand-Alone unassisted. In some cases, however, a certain amount of training will be required and should be anticipated. Patients with lesions above T8 will probably require some degree of assistance. Quadriplegics or others with upper-extremity involvement will require assistance.

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The standing position permits patients to reach high objects that would be difficult or impossible to reach from a wheelchair. This is a potentially valuable asset for many patients, in particular, the invalid housewife while performing kitchen activities; however, this convenience is offset to some extent by the inability to reach objects on the floor when standing in the device.

Although the energy cost of operating the Stand-Alone is greater than that required for the wheelchair, it cannot be considered excessive. The Stand-Alone is not designed for relatively long runs as is the wheelchair. The laboratory test represented a more intense level of operation than might normally be expected; although a rate of approximately 10 strokes per minute might be employed, it is doubtful that the normal use pattern would be prolonged for 7 consecutive minutes. After the first stroke, approximately 23 percent of the energy output is used to overcome friction.

The Stand-Alone provides excellent mobility and maneuverability, i.e., all subjects tested were able to perform all of the selected self-care activities with a minimum of difficulty.

The device is very stable and safe on level ground, but caution should be exercised as the center of gravity of the man-machine approaches the front axles on inclines of greater than 8° in slope.

Starting-force requirements appear not to be excessive and compare favorably with those of wheelchair propulsion.

Patient reaction to the Stand-Alone was quite positive. Several subjects offered constructive criticism, but all felt that the device was extremely convenient for standing.

FIELD TEST OF STAND-ALONE THERAPEUTIC AID

Purpose of Field Test

The field test of the Stand-Alone Therapeutic Aid was designed to evaluate the effectiveness of the device in the medical treatment of patients with certain disabilities. It was undertaken with the hope that sufficient information would be obtained upon which to formulate a decision as to whether the device should be issued to certain patients, and if so, the indications and contraindications for such issuance.

Design of Field Test

Five Stand-Alone devices were purchased by the VA Prosthetics Center and, after thorough inspection, one model was made available to each of the five participating stations. Copies of the manufacturer's leaflet were sent with the device. Each station was requested to test the Stand-Alone on as many patients and for as many disabilities as might be feasible over a 6-month period. It was emphasized that only those subjects who were deemed by a physician to be ready and able to assume an upright

position were to be permitted to use the Stand-Alone. Moreover, a medical judgment was requested with respect to the duration and frequency of standing by a given patient in the device.

A system of reporting was developed to yield data regarding the experiences of individual subjects over a maximum period of 3 months' use with the device. Reports were sent to the Project Director in New York through the appropriate Area Medical Offices.

Information Sheet, IS 2–1, was distributed to all participating stations, explaining in detail the purposes and procedures of the field test.

Reports

Two types of reports were utilized in the study: CAS 2–1 *"Selection Record"* and CAS 2–2 *"Followup Report."*

The Selection Record was prepared and forwarded to the Project Director at the time a subject was selected for the test. The Followup Report was prepared on two occasions: 1 month after the subject initially began to use the device, and again, 3 months after such initial use. If a subject withdrew before the final 3-month report, a report was to be designated as "Final," covering the period after the 1-month followup and the date of withdrawal from the study.

Subjects Participating in Field Test

The distribution of Selection Record forms CAS 2–1 received from the field was as follows: 6 from VAH, Hines, Ill.; 10 from VAH, Long Beach, Calif.; 7 from VAH, Memphis, Tenn.; 7 from VAH, Richmond, Va.; and 11 from VAH, West Roxbury, Mass.

Of these 41 cases, Selection Records for five subjects were received too late for inclusion in this report. Four other cases were withdrawn before they could undertake use of the device. Thus, this field test report covers a sample of 32 subjects for whom appropriate reports became available. It should be noted that all of these subjects were hospitalized patients during the course of study. (Separate coverage is given to the case followed by the Brooklyn Outpatient Clinic, N.Y., and to the one reported on by the VA Hospital in Coral Gables, Fla., also on an outpatient basis.)

Characteristics of Sample

According to the manufacturer's assertion, the Stand-Alone offers therapeutic advantages for "partial or total paraplegics and partial quadriplegics" and for "neuromuscular disabilities which do not permit adequate balance or locomotion." The five participating hospitals were requested to select patients with such disabilities as subjects for the study but not necessarily to limit their selection only to patients with these involvements. Tables 4 and 5 present disability distribution data for the 32 subjects who participated in the study.

Tables 6–8 summarize some of the other characteristics of the 32 subjects who participated in the study.

TABLE 4.—*Disability Distribution*
(N=32)

Code [a]	Disability	Number of Cases
A	Traumatic quadriplegia	7
B	Nontraumatic quadriplegia	2
C	Traumatic paraplegia without trunk or arm involvement	6
D	Traumatic paraplegia with trunk and arm involvement	1
E	Traumatic paraplegia with trunk and without arm involvement.	10
F	Nontraumatic paraplegia with trunk and without arm involvement.	4
G	Arteriosclerotic heart disease; cervical discogenic disease; cardiovascular accident.	1
H	Multiple sclerosis	1
	Total number of cases	32

[a] Disability codes arbitrarily assigned for convenience of reporting.

TABLE 5.—*Disability Distribution—by Station*
(N=32)

Station	Disability Codes [a]								Total
	A	B	C	D	E	F	G	H	
Hines, Ill	2	....	2	....	2	....	....	....	6
Long Beach, Calif	....	1	....	....	....	4	1	1	7
Memphis, Tenn	....	1	1	....	2	....	....	....	4
Richmond, Va	3	....	1	....	3	....	....	....	7
West Roxbury, Mass	2	....	2	1	3	....	....	....	8
Total	7	2	6	1	10	4	1	1	32

[a] Disability codes arbitrarily assigned for convenience of reporting.

TABLE 6.—*Subjects' Disability, Age, and Duration of Disability*
(N=32)

Case No.	Disability	Disability Code [a]	Age	Number of Years Disabled
2	L1 paraplegia complete, with neurogenic dysfunction of the bladder and bowel; healed supracondylar fracture left femur.	C	57	5¼
4	T9 paraplegia complete, with neurogenic dysfunction of the bladder and bowel.	C	34	13
5	Fracture C6–7–T1; plane crash 1942. Quadriplegia; below C7, with neurogenic dysfunction of bowel and bladder.	A	50	4
7	Fracture T4; auto accident 1962; transsection of cord; with complete loss of function below T5.	E	31	1¼
8	Complete loss of sensory and motor function below T5, with neurogenic dysfunction of bowel and bladder.	E	37	2¾
10	Quadriplegia, C7–8; Sept. 1959; traumatic.....	A	25	4½
11	Paraplegia, T6; injury sustained in fall down an elevator shaft, July 1962.	E	47	2
12	Paraplegia, L1–2; accident sustained in Aug. 1953; left nephrectomy in 1962.	C	37	10½
13	Paraplegia; fracture dislocation of vertebral column, L3–4.	C	38	11½
14	Paraplegia, T10–11; injury sustained in an accident on Aug. 9, 1962, on National Guard Duty.	E	29	1¼
15	Incomplete quadriplegia with partial function in upper extremities and some in lower extremities; injury sustained on July 7, 1962.	A	23	1½
16	Postpoliomyelitis; essentially a paraplegic.....	F	27	4½
17	Multiple sclerosis.....	H	46	18
18	Transverse myelitis, T10; myositis ossificans, left hip; fixation of hip in extension; paraplegia.	F	41	2½
19	Multiple myeloma; paraplegia.....	F	48	1½
20	Arteriosclerotic heart disease; cervical discogenic disease; cardiovascular accident.	G	62	2½
21	Postpoliomyelitis; partial quadriplegia.....	B	46	2½
22	Myelopathy, C6; partial quadriplegia.....	B	34	12½
24	Paraplegia T7–8; traumatic.....	E	19	¾
25	Spinal cord injury fracture T1; full motor function of upper extremities with numbness of ulnar distribution.	E	45	19
26	Cervical injury; quadriplegia.....	A	25	2¾
27	Accidental gunshot wound of the T12–L1 interspace, sustaining *incomplete* myelopathy at the level T12. Also return of sensation in the upper third of his left thigh and power in left hip area in flexion, abduction, and adduction.	C	37	1

See footnote at end of table.

TABLE 6.—*Subjects' Disability, Age, and Duration of Disability*—Continued
(N=32)

Case No.	Disability	Disability Code [a]	Age	Number of Years Disabled
28	Myelopathy, caused by epidural abscess; paraplegic (spastic).	F	18	¾
29	Traumatic paraplegia, L1, incomplete; arteriosclerotic heart disease.	C	75	½
30	Traumatic paraplegia, T8	E	47	7½
31	Traumatic quadriplegia, C7	A	46	3½
32	Traumatic quadriplegia, C6	A	42	6¾
33	Traumatic paraplegia, T5	E	21	1
34	Traumatic paraplegia, T8	E	32	4½
35	Traumatic quadriplegia, C6	A	28	5
36	Paraplegia complete, T8; from shrapnel	D	53	19
37	Paraplegia, T7; traumatic; diabetic	E	49	18

[a] Disability code arbitrarily assigned for convenience of reporting.

TABLE 7.—*Education, Usual Occupation, and Number of Cases Employed*

Education, Occupation, Employment	Number of Cases	Education, Occupation, Employment	Number of Cases
Years of Schooling:		*Years of Schooling*—Continued	
5–6	2	17+	1
7–8	2	Unknown	1
9–10	4		
11–12	14	Total number of cases	32
13–14	5	Range: 5–20 yr	
15–16	3	Average: 11.8 yr.	
Usual Occupation:		*Usual Occupation*—Continued	
Professional or semiprofessional	0	Skilled	6
Managerial and official	2	Semiskilled	5
Clerical and kindred	2	Unskilled	2
Sales and kindred	2	Student	4
Service	4	Retired	3
Agricultural, horticultural, and kindred	1	Unknown	1
		Total number of cases	32
Employed:		*Employed*—Continued	
Yes	4	Student	4
No	21		
Retired	3	Total number of cases	32

TABLE 8.—*Age, Height, and Weight of Subjects*

Age, Height, and Weight	Number of Cases	Age, Height, and Weight	Number of Cases
Age (yr.):		*Age (yr.)*—Continued	
15–19	2	55–59	1
20–24	2	60–64	1
25–29	5	75–79	1
30–34	4		
35–39	4	Total number of cases	32
40–44	2	Range: 18–75 yr.	
45–49	8	Average: 39 yr.	
50–54	2		
Height (in.):		*Height (in.)*—Continued	
66–67	4	74–75	2
68–69	13		
70–71	8	Total number cases	32
72–73	5	Range: 66–75 in.	
		Average 70 in.	
Weight (lb.):		*Weight (lb.)*—Continued	
130–134	4	175–179	2
135–139	2	180–184	2
140–144	3	185–189	2
145–149	2	190–194	0
150–154	4	195–199	1
155–159	2		
160–164	3	Total number of cases	32
165–169	4	Range: 130–195 lb.	
170–174	0	Average: 156 lb.	

Analysis of Data

In response to a question on the final Followup Reports, 24 subjects indicated that they liked the device while 8 replied in the negative. In a number of cases, however, other reported considerations tended to modify these responses. In fact, some of the subjects who responded in the affirmative would probably not wish to use the device nor would it be beneficial for them to do so. Amplification of these Yes-No responses is undertaken later in the report; they are cited here to provide an early overview of the general acceptance of the device by the 32 subjects and as a frame of reference with which to consider some of the data which follow.

Use Data. Tables 9–11 give information on other mobility aids used, living conditions, and daily standing habits of the patients. Table 12 presents data on the number of hours the device was used by all subjects.

It should be recalled that only one device was available at each hospital

participating in the study; furthermore, some subjects were discharged from the hospital prior to 3 months of use or otherwise withdrew from the study. The schedule of use varied with each subject. Some used it once a week, others daily; except for three cases, however, all tried the device once daily. Most subjects used it for 1 hour at a time, except for the 8 subjects who reported that they did not like the device. The range of use for this latter group was from 6 to 60 minutes. The subject (Case No. 7) who used the device for the least amount of time, namely 1¼ hours, had to be withdrawn from it because he felt faint and was unable to breathe.

TABLE 9.—*Types of Aids Used Outside of Hospital Setting*

Devices Used (including automobile)	Number of Cases	Devices Used (including automobile)	Number of Cases
Wheelchair	18	*Drive car:*	
Wheelchair, braces	2	Yes (with aids)	14
Wheelchair, trapeze	1	No	18
Wheelchair, crutches	2		
Wheelchair, knee spreader	1	Total number of cases	32
Wheelchair, braces, canes	1		
Wheelchair, braces, crutches	2		
Wheelchair, parallel bars, braces	1		
Information not supplied	4		
Total number of cases	32		

TABLE 10.—*Usual Living Quarters and Home Assistance*

Living Quarters and Assistance	Number of Cases	Living Quarters and Assistance	Number of Cases
Usual Living Quarters:		*Assistance Available at Home:*	
Standard	14	Yes	17
Special adaptations	9	No	15
Hospital [a]	9		
		Total number of cases	32
Total number of cases	32		

[a] Accuracy of these responses is questionable.

Entering and Leaving the Device. A major concern of the field test had to do with the problems encountered by the subjects in entering and leaving the Stand-Alone device. The manufacturer's manual, which included instruction along these lines, was made available to each station. Unfortunately, it was necessary for us to suggest a number of revisions and

clarifications in areas where the manual was inadequate. No indoctrination program was conducted for the personnel co-operating in the study with respect to the operation of the device. They had to rely upon the materials sent by our office and on their own insights regarding the design and function of the device.

TABLE 11.—*Standing Regimen*

Home and Hospital	Number of Cases	Home and Hospital	Number of Cases
At Home:		*In Hospital:*	
Yes (up to 1 hr. daily)	6	Yes	28
No	22	No	4
Hospitalized since becoming disabled	4	Total number of cases	32
Total number of cases	32		

TABLE 12.—*Number of Hours Device Was Used*

Hours Device Used	Subjects Who Liked Device	Subjects Who Did Not Like Device
1–10	2	5
11–20	6	1
21–30	3	1
31–40	3	1
41–50	1	0
51–60	2	0
61–70	2	0
71–80	1	0
81–90	2	0
201–210	1	0
271–280	1	0
Total	24	8
	Range: 2–280 hr.	Range: 1¼–39 hr.

The Two Methods of Entering the Stand-Alone

In the Tilt-up Method (Plan No. 1), the front of the wheelchair is brought as close to the Stand-Alone as possible and all brakes are locked for stability in transfer. The patient moves as far forward as possible on the edge of the wheelchair seat, raises the Stand-Alone assistance seat, and then slips the seat brackets into the mounting hinges of the frame. With

his feet properly strapped in the footpan, he moves forward on the assistance seat until both knees rest snugly against the kneepads. With his left hand on the handgrips, the patient reaches down with his right hand to grasp the sideframe near the right front wheel. He then tilts himself up into a semistanding position and reaches back with one hand to drop the backrest bar into place, locking it securely before raising his torso to the full upright standing position. The chest-rest bar should be locked into position.

In the Pull-up Method (Plan No. 2), the brakes of the Stand-Alone are locked and the assistance seat is slipped into place first so that the patient can put his feet on top of the seat. Only then is the wheelchair moved as close as possible to the Stand-Alone, sliding the patient's legs forward until his feet rest in the footpan. After locking the wheelchair brakes, the patient then slides all the way onto the assistance seat from the wheelchair, adjusts the footstraps, and then sets his knees forward within the kneepads. He then places his arms on top of the sideframes and, grasping the handgrips, pulls himself up to a semistanding position. After dropping the backrest bar into position and securing the locking device, he assumes the full upright standing position. The chest-rest is then locked into position as described in Plan 1, and the patient is ready to move the device.

The Pull-up Method (Plan No. 2) is recommended by the VA evaluation groups. Twenty-three of the 32 subjects needed assistance entering and leaving the device. The 9 subjects who did not require assistance used "Plan 2" as described in the manual, with varying modifications of the technique. The most common deviation from "Plan 2" consisted in pulling to the erect position directly from the wheelchair instead of transferring initially to the seat.

The disability codes of the 9 subjects who did not require assistance were as follows: two cases each in A, C, E, and F categories, and one case in G.

Of the two traumatic quadriplegia cases (Code A), one had impairment of finger function but had adequate hand function to control various parts of the device. He would lift the seat, draw the wheelchair close to the Stand-Alone, place his legs as far forward as possible, hook his wrists behind the curve of the handlebars and hoist himself into a standing position. Although that patient was designated as a quadriplegic, it is obvious that he retained considerable upper-extremity and trunk function.

The other quadriplegia case was designated an incomplete quadriplegic. The technique he used was similar to "Plan 2," recommended for paraplegics in the manufacturer's manual.

Difficulties Encountered. The difficulties encountered by the 23 other subjects, including 7 of the 8 subjects who did not like the device, may be categorized as follows:

1. Physical inability to assume the upright position independently or to maintain this position while securing the supports (19 cases).

2. Difficulty in securing and removing the support mechanisms (3 cases).

3. Return of sensation in the lower extremities caused hypersensitivity when the lower extremities contacted parts of the device (1 case).

Difficulty in adjusting the Stand-Alone to hold the user in a firm, upright position was reported by attendants in four cases, three of whom were quadriplegics. In one case, it was reported that the "Patient is a tall individual (6 ft. 3 in.) who is very unstable in the erect position; therefore a pad has to be placed between his hips and the sidebars for protection."

Confidence and Comfort. Only 2 of the 32 subjects reported that they did not feel confident in the device. In both cases, it was reported that they had had a history of shortness of breath and feelings of faintness at times when in an upright position.

With respect to comfort, 6 subjects replied in the negative. The reasons cited for their lack of comfort included "Spasm"; "Difficulty in breathing, blackouts"; "Unable to breathe, feels faint"; "Back pain after standing for 20 minutes"; "Felt cramped."

Use of the Seat. Twelve of the 32 subjects sat on the seat provided between periods of standing. The range of sitting time was from 1 to 5 minutes. Among the 12 subjects who sat for short periods, 6 reported discomfort primarily because the kneerest and the seat were too close together.

Seven of those 12 subjects experienced difficulty changing from the standing to the sitting position. Two were quadriplegic subjects (Code A) whose attendants admitted being unable to position themselves properly to allow the patients to shift to the sitting position. A third quadriplegic (Code A) had difficulty in sitting and required assistance. Three subjects reported difficulty in maintaining balance while unlocking supports. The seventh subject (Code E) became weak and faint from loss of breath and had to be assisted to the sitting position.

An additional 11 subjects indicated that they experienced difficulty in changing from standing to sitting. The most common difficulty experienced had to do with inability to remove locking pins. It is our understanding that the manufacturer has replaced the locking pins with a locking clasp which slides in and out of position.

Maneuverability of Device. Only 2 subjects, both quadriplegics, indicated that it was not easy to maneuver the Stand-Alone. Both were 6 ft. 3 in. tall and had difficulty in reaching the handwheels to move the device.

Outdoor Use of Device. The participating stations were permitted to have the device used outdoors, but they were requested to avoid having it used for climbing and descending curbs. The device was used outdoors by 13 subjects, and 5 reported problems with such use; their problems are outlined in Table 13.

TABLE 13.—*Outdoor Use of Device*

Disability Code	Case No.	Subject Reaction
C.....	13	Found the device fatiguing on rough terrain.
C.....	27	Reported that he was sensitive to jarring when wheels bumped any object.
E.....	25	Felt insecure when on ramps; felt off-balance.
F.....	18	Felt device was unstable on uneven surfaces, having noticed back wheels leaving the surface.
H.....	17	Observed some degree of instability when over uneven surfaces; back wheels tended to leave the surface.

Braking Mechanism. The braking mechanism on the Stand-Alone is actually a locking device. Eight subjects reported difficulty with the mechanism. Inconvenient positioning of the handle was cited by 4 subjects; an insufficient number of locking positions was reported in four other cases. In one of the stations it was noted that, with the brakes locked, there was a tendency for the device to slide on the polished floor while the subjects were entering it.

Stability. The device was consistently deemed to be stable. No tipping fore or aft or sideways was reported. The comment about sliding, with the brakes locked, on a polished floor was again noted.

Physical Injury or Impairment to Users. No evidence of damage or injury to the subjects was reported by any of the participating subjects. Nor was there reported any deterioration to the patient's physical condition. In one instance where there were some difficulties in getting the patient into a firm upright position, there was contact with one hip on the front crossbar, and the insertion of a rubber pad helped the situation.

Fatigue as Compared with Wheelchair. Extensive coverage of this aspect was presented earlier. The listing here is limited to the responses offered to the question: "As compared with the use of a wheelchair, does the Stand-Alone fatigue the patient more, less, or to the same extent?" Data are presented in Table 14.

TABLE 14.—*Fatigue as Compared with Wheelchair Use*

Degree of Fatigue	Number of Cases	Degree of Fatigue	Number of Cases
More fatiguing than wheelchair.	11	Information not supplied.....	2
Less fatiguing than wheelchair..	0		
Same extent.....	19	Total number of cases.....	32

Six of the 11 subjects who found the Stand-Alone to be more fatiguing than a wheelchair were quadriplegics. Fatigue seemed to be closely related to "liking" the device since 6 of the 8 subjects who reported that they disliked it also found it more fatiguing. Some of the reasons given for the increased fatigue were as follows:

Quadriplegics: "Prolonged standing;" "Back support inadequate;" "Standing for the first time in 9 years." Paraplegics: "When used on rough terrain."

Functional Failures. There were no reported instances of any failure of the device to function properly. No breakdown of components occurred.

Effect on Attitudes, Activities, and Physical Condition of Subjects

General Attitude Toward Device. A specific question was asked as to whether the patient liked the Stand-Alone device. As has been mentioned previously, such discrete, subjective Yes-No responses are not necessarily compatible with the other findings. Table 15 shows the distribution by station of the responses.

Since only 8 subjects were involved who indicated that they did not like the device, a short background statement on each may be helpful.

TABLE 15.—*"Does the Patient Like the Stand-Alone Device?"*

Station	"Yes" Responses	"No" Responses
Hines, Ill	6	0
Long Beach, Calif	8	0
Memphis, Tenn	1	3
Richmond, Va	3	4
West Roxbury, Mass	6	1
Total number of cases	24	8

Case No. 22: A 34-year-old male, nontraumatic quadriplegic, level C6, for 12½ years, had not stood in 9 years. He was 6 ft. 3 in. tall, and had difficulty reaching the handrims. Although he had some functional return in upper extremities, he had no grip in hands; this weakness necessitated assistance in entering and leaving the device. Although the patient thought he might like the device because of the value to be derived from standing in it, once the novelty wore off he began having trouble as he began to increase his time of use and activity. Severe spasm and muscle contractures contributed to his difficulties; however, standing in the device did tend to relax spasm in the trunk and lower extremities for several hours after each session. His experience of 8½ hours with the device resulted in an increase in his standing tolerance.

Case No. 24: An 18-year-old male, traumatic paraplegic, level T7–8, for 9 months. This patient needed no assistance entering and leaving the device but had difficulty with the locking pins. He complained of back pain after standing from 20 to 25 minutes. He commented that the leverage was not as desirable as compared with the wheelchair (he is 6 ft. tall). Stand-Alone was found more fatiguing and uncomfortable than a wheelchair. He reported that the Stand-Alone had no advantages over the wheelchair other than standing. His total use time was 3½ hours.

Case No. 25: A 44-year-old male, traumatic paraplegic, level T1, for 19 years. Prior to his experience with the Stand-Alone, the patient had not stood for 2 years. Employed as a part-time bookkeeper, he initially liked the device because of its novelty but then lost interest; he used the device for 39 hours but by the end of 1-month followup was unable to overcome feelings of nausea when in the device. The patient experienced difficulty in maintaining himself in the forward position while placing backrest and pin, and he required aid in pulling himself into the upright position or lowering himself from the standing position. He felt insecure on a ramp because of a feeling of "off balance." The subject was comfortable in the device for only 1 hour.

Case No. 31: A 45-year-old male, traumatic quadriplegic, level C7, since June 1960, used the Stand-Alone for a total of 20 hours and needed the assistance of two people because of his instability; attendants found it difficult to help him. The patient felt cramped in the Stand-Alone and was uncomfortable when sitting. For his particular use at home, patient felt that the device would not be practicable.

Case No. 32: A 43-year-old male, traumatic quadriplegic, level C6, for 7 years, had only a fifth-grade education. Hospitalized since 1957, he used the Stand-Alone for a total of 10 hours. He needed assistance because of inability to use his hands, and was uncomfortable in the device because of spasm of lower extremities. The design features made it difficult to assist the patient, who found the device more fatiguing than a wheelchair.

Case No. 23: A 21-year-old male, traumatic paraplegic, level T5, for one year, used the Stand-Alone for a total of 30 hours. He experienced difficulty in entering and leaving the device because of spasticity, and he had trouble adjusting the supports because of inability to stabilize himself. He was, however, confident and comfortable in the device when standing, but he could not sit comfortably because of the placement of the seat. The patient believed that the device would not be practical for use at home.

Case No. 35: A 35-year-old male, traumatic quadriplegic, level C6, for 5¼ years, hospitalized since 1959, stood for periods of from 45 to 60 minutes strapped in a conventional standing frame. He used the Stand-Alone for a total of 4 hours. Although the subject had difficulty getting into and leaving the device because of his disability, once in, he could stand confi-

dently and comfortably; sitting was uncomfortable, however, because of seat placement. He felt that the Stand-Alone fatigued him to the same extent as did a wheelchair, but because of the amount of assistance required, he thought that the Stand-Alone would not be practical for him.

Case No. 7: A 31-year-old male, traumatic paraplegic, level T4, for 1½ years, had trunk involvement but no impairment of the upper extremities. He did not follow a standing regimen at home, and used the Stand-Alone for only 1¼ hours. He discontinued its use because of loss of breath and faintness. It is reported that he was similarly affected when in a near-perpendicular position in a tilt table.

Reported Change in Outlook or Attitude. Ten subjects reported a change in outlook or attitude that could be reasonably related to their use of the Stand-Alone device. For 9 of these subjects, the change was in a positive direction. The tenth subject was disappointed in his inability to use the device because of breathing difficulty and feelings of faintness. He was the only one in this group of 10 subjects to indicate that he did not "like" the device. A listing of the attitudes expressed by the other 9 subjects may be helpful:

Quadriplegics (Disability Code A): Case No. 10: "Patient is very pleased with the prospects of activities this device opens to him."

Case No. 15: "He finds it more encouraging and gratifying in being able to do things while in the device which he could not do sitting in a wheelchair."

Case No. 26: "Patient has stated that he would be more apt to stand with this device than with crutches and braces."

Paraplegics (Disability Code C): Case No. 2: "Formerly was not receptive to program of exercise or standing; now stands and moves about willingly."

Case No. 12: "The restrictions of the physical disability are less irksome."

Case No. 13: "Finds the disability less cumbersome and enlarging his scope of diverse function."

Paraplegics (Disability Code E): Case No. 8: "Patient looked forward to his daily period in the Stand-Alone and was enthusiastic about moving around in the erect position."

Case No. 11: "Patient is highly pleased with the opportunities that the Stand-Alone opens to him in allowing him to cope with his duties in his machine shop."

Case No. 14: "A greater sense of satisfaction is experienced from doing things that the patient could not do without this device."

Noted Improvements in Physical Condition of Subjects. The participating stations were requested to report any improvements in the physical condition of the subjects, which could be reasonably related to their use of the device. In 9 of the 32 cases, improvements were noted. Table 16 presents the reported data on physical improvements.

TABLE 16.—*Noted Physical Improvements*
(N=9)

Disability Code	Case No.	Approx. No. of Hours of Use	Reported Change(s)
A	15	280	"Improving his sense of well-being and strength of upper extremities."
B	22	8½	"More tolerance in the standing position; standing tends to relax spasm in the trunk and lower extremities for a short period of several hours thereafter."
C	12	64	"A general sense of well-being and contentment."
C	13	60	"General sense of well-being."
E	8	90	"Spasm was less noticeable when patient was in Stand-Alone as compared to when he was standing with braces in parallel bars."
E	14	84	"A general sense of physical well-being and muscle strength of arms."
E	25	39	"Patient can stand in Stand-Alone now without becoming sick."
F	18	60	"Patient developed some degree of standing tolerance in addition to general endurance. Pressure on sacral and gluteal decubiti was relieved."
F	19	210	"Confidence in being in the erect position prior to attempting ambulation."

Benefits and Newly-possible Activities as Reported by Users. An attempt was made to elicit information from the subjects as to activities they could undertake by use of the Stand-Alone, which were formerly impossible. In addition, their opinions were obtained as to the benefits the device can provide outside a hospital setting. Table 17 summarizes the responses of 27 subjects.

Medical Findings

HINES (Six cases):

Prescription of Device. Would prescribe Stand-Alone device in cases of spinal-cord injuries, particularly paraplegia. Would also prescribe device for quadriplegics who have enough function to enter and manipulate the device. Patients should be well motivated. Device considered where patient's employment or other pursuits would render it very useful.

Contraindications and Precautions. No special contraindications as long as the patient has enough function to stand in device and endurance enough to use it for the time required.

Care should be taken to position the feet properly to allow good leverage in assuming the erect position. Standing position should be comfortable.

Normally-used Aids Which Could Be Eliminated by Use of Stand-Alone. The Stand-Alone might be used instead of the following aids: braces, when they are used solely for standing; standing frame or tilting table; parallel bars; and possibly spare wheelchairs.

TABLE 17.—*Responses by Subjects as to Benefits and Activities*
(N=27)

Disability Code	Case No.	Comments
A	5	"Requires less space than tilt table or parallel bars; provides mobility at patient's discretion in contrast to tilt table and parallel bars."
A	10	"Patient anticipates using device in his garden, in painting house walls, and for reaching objects normally outside his reach."
A	15	"Device permits patient to stand for longer periods while moving around and increases his scope of activities. Can get near machinery and reach for objects."
A	26	"Finds device convenient to get into; derives self-satisfaction; can reach objects, particularly overhead."
A	31	"Patient is able to move about in standing position but does not like the device because he feels that for his particular use at home it would not be practicable."
B	21	"Gave patient an opportunity to mobilize in an upright position. Though he liked it, he felt that too much assistance was required and that the device therefore would not be useful for him at home."
C	2	"Easier for him to use than other devices; can stretch and get around better; would be useful for urinary drainage."
C	4	"Liked the device to a certain extent because it gave him a chance to stand up in a way altogether different than with braces." (Doctor indicated patient showed little interest in standing activities in the past and did not follow through with standing during the test.)
C	12	"Subject could stand while in motion; reach for otherwise inaccessible objects."
C	13	"Subject could stand while in motion; reach for otherwise inaccessible objects."
C	27	"Motivated patient to participate in manual arts therapy; felt that device might be useful to him in his job."
C	29	"Able to move around while standing; felt it would be useful around home as a means of weight-bearing and mobility."
D	36	"Was able to get into the erect position faster and easier than with braces; would be able to derive benefits from standing without use of braces and parallel bars."
E	8	"Felt safe, and at the same time derived the same benefits from standing, stretching, and pressure relief that he used to get when standing with braces in parallel bars. Will continue to stand in Stand-Alone device which he would not do if he had to don braces and erect parallel bars in his home."

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TABLE 17.—*Responses by Subjects as to Benefits and Activities*—Continued

(N=27)

Disability Code	Case No.	Comments
E	11	"Confident that Stand-Alone will increases his activities."
E	14	"Would be able to do many things, especially in yard and workshop; perform minor home repairs and reach objects otherwise not accessible."
E	24	"Able to move around in Stand-Alone, but was uncomfortable and tired when he moved around long distances."
E	30	"Could reach high objects; freedom of movement in erect position."
E	33	"Benefit from moving about while standing; however, difficult to get into and not practical for use in his home situation."
E	34	"Perform craft work while standing, provide mobility while standing."
E	37	"Allowed standing without need for bracing or bars; removed pressure from buttocks; would use it for activities at home."
F	16	"Beneficial to assume the upright position for short periods of time. Liked the device only because of its novelty."
F	18	"Work in the upright position in electronics shop; can mobilize in upright position; has recently acquired hip flexion; prefers wheelchair."
F	19	"Able to maneuver in upright position."
F	28	"Able to maneuver in upright position; however, because of his home situation, felt this device would be another therapeutic appliance with minimal use."
D	20	"Move around in upright position; however, somewhat impractical for him due to physical characteristics of his home."
H	17	"Able to move around in upright position; however, because of his paralytic involvement, very little benefit can be derived from Stand-Alone outside of hospital setting."

LONG BEACH (Seven cases):

Prescription of Device. Would consider prescribing the device in specific instances for paraplegics with good extremities and without deformities of the lower extremities. In certain reversible conditions, the device can serve to help patient build tolerance and endurance to standing as he recovers from his illness. In cases where recovery is not expected, it can serve to place them in upright position and permit them to engage in certain work activities, with psychological as well as practical benefits.

Contraindications and Precautions. For spastic and incoordinated individuals. Device should not be used on uneven surfaces, inclines, or curves.

Normally-used Aids Which Could Be Eliminated by Use of Stand-Alone. Device does not eliminate need by the patient for equipment such as a wheel-

chair, and usually it cannot be considered a substitute for long-leg braces. It does supplement the therapeutic armamentarium.

MEMPHIS (Four cases):

Prescription of Device. Would prescribe it only in very isolated cases, namely, paraplegics whose work requires standing and use of hands, and who travel minimal distances; would not use the device in standing programs, either at home or in hospital. Mobility of device is wasted on quadriplegics because they cannot effectively use the device.

Contraindications and Precautions. Avoid sloping terrain which results in lateral tilt of the device.

Normally-used Aids Which Could Be Eliminated by Use of Stand-Alone. None.

RICHMOND (Seven cases):

Prescription of Device. Would not prescribe the device for patients with traumatic injuries to the spinal cord because wheelchair accomplishes mobility, and parallel bars or standing frame accomplishes the standing position more economically and with less physical effort for user and attendant. Device may have vocational usefulness.

Contraindications and Precautions. None recorded.

Normally used Aids Which Could Be Eliminated by Use of Stand-Alone. None.

WEST ROXBURY (Eight cases):

Prescription of Device. Would prescribe Stand-Alone for most paraplegic and partial quadriplegic patients who can maneuver the apparatus adequately and feel they can derive benefit from it. Benefits derived from standing for cord-injury patients are well documented.

Contraindications and Precautions. (a) The skin should be free of lesions at the pressure-support areas; (b) Physician should satisfy himself that the patient can maintain himself in the upright position without deleterious hypotensive effect; (c) In cases where breathing difficulties develop; and (d) For those patients who, for psychological and physiological reasons, can ambulate with braces.

Normally-used Aids Which Could Be Eliminated by Use of Stand-Alone. Spare wheelchairs. Standing frame, tilt table, parallel bars—in the home.

Summary of Field Test

The experiences of 32 male subjects using the Stand-Alone device for periods ranging from 1¼ to 280 hours were reported by 5 VA hospitals having spinal-cord injury services. Only one device was available at each participating station, thus presenting limited availability of the device for each subject. The average use time per session was 1 hour. No formal

orientation programs were conducted for the personnel cooperating in the study; they were simply sent informational material and appropriate forms. The duration of the onset of disabilities ranged from less than 1 year to approximately 19 years. Some of the subjects were long-term hospital cases.

The data show that most of the patients, as well as most of the participating physicians, accepted the Stand-Alone device as a means of achieving mobility while standing. The ability to reach otherwise inaccessible objects and perform meaningful tasks while standing was a commonly reported advantage. The therapeutic advantages from standing were cited.

Despite the advantages afforded by the Stand-Alone device, the severe physical limitations of some of the patients reduced their effective utilization of the device. The design of the device presented further difficulties for some of the subjects as well as for the attendants, particularly in the cases of quadriplegia.

A highly critical precaution had to do with the readiness of the subject to assume an upright position. Instances of nausea, dizziness, and difficulty with breathing were reported in cases where it was apparent that the subjects were not ready for the vertical position.

The majority of the subjects required assistance entering and leaving the device. The subjects in such instances were primarily cases where there was trunk, arm involvement, or a marked spasticity of the lower extremities.

There was no reported evidence of breakdown of components throughout the study. This factor must be considered, however, in terms of the protected environment in which the devices were used.

The majority of the doctors indicated that they would prescribe the Stand-Alone device selectively. In some cases, certain aids that are normally prescribed might be eliminated. In a hospital situation the device can be considered only as a supplement to the therapeutic armamentarium.

SUMMARY OF BROOKLYN, N.Y., OUTPATIENT CLINIC EVALUATION

Background

Independent of the field test reported above, the Brooklyn Outpatient Clinic conducted an intensive followup of a veteran using the Stand-Alone outside of a hospital setting for approximately 10 months. The thoroughness of this followup evaluation, which included visits to the subject's home, warrants a summary of the Brooklyn experience. The Acting Clinic Director, the Chief, Neurology Treatment Division, the Chief, Physical Medicine and Rehabilitation, and the Chief, Prosthetic and Sensory Aids Service participated in the evaluation.

It should be noted that the initiation of this evaluation antedated our laboratory evaluation and field test. The subject was furnished a Stand-

Alone device on Oct. 10, 1962, for trial use and evaluation. A final evaluation was accomplished on Oct. 3, 1963, almost a year later; however, there were some intervals of from 6 to 8 weeks when, because of the veteran's travel both in the United States and abroad, the device was not used. Approximately 10 months of use are therefore involved in this evaluation.

Early Modifications to the Device

In October 1962, at the request of the Brooklyn Outpatient Clinic, the VA Prosthetics Center made the following modifications to the Stand-Alone to accommodate the subject:

1. Adjustable (Velcro) shoe-retaining straps were fabricated on the foot tray to prevent the patient's feet from shifting.
2. The edges of the foot tray were rolled over to minimize the possibility of the patient's injuring himself on the sharp edges of the tray.
3. The brake disk was reinforced to insure proper engagement of the brake lever.
4. To prevent the patient's back from coming in contact with the backrest frame, foam padding was added to the backrest so that it extended over the metal frame.

The Subject

Subject is a 34-year-old, married, male veteran. As a result of an automobile accident in August 1949, his disability is as follows: Myelopathy transverse, complete, secondary to compression fracture of vertebrae T3–4, manifested by loss of motor and sensory function of both lower extremities and loss of bladder and bowel function.

The patient is 6 ft. 2 in. tall and weighs 150 lb.; he has no need for an attendant at home, and he lives in an apartment several floors above street level. He is currently working toward his doctorate in economics at Columbia University, and travels extensively both for personal reasons and in connection with Paralyzed Veterans Association duties. The subject does not use the Stand-Alone when he travels.

Summary of Brooklyn Evaluation Report

Although four earlier reports were submitted, it is deemed sufficient to limit this summary mainly to the final report submitted by the Brooklyn Outpatient Clinic, dated October 3, 1963.

> Subject has been able to get in and out of the device without assistance. He has utilized it to get about a normal apartment without need for any alterations. It is reported that he was able to open the door to greet evaluators from the Brooklyn Clinic. It has not been feasible for the subject to take the device down to the street; if it were, he reports that he would have no difficulty in making use of it outdoors. During the 10 months of use, there was no breakdown of the device.

Some of the observations expressed by the subject in November 1962 may be of interest:

a. *Physical Characteristics.* The device is quite easy to enter or leave. It has structural stability in that it is impossible to tip. With the exception of the modifications already made, at the suggestion of Dr. _____, I would only suggest slightly more durable parts, such as nuts, bolts, etc. I would also suggest a better system of stops for the front and back supports.

b. *Physical Effects.* The use of the Stand-Alone has served wonderfully as a method of controlling my spasms and has helped my elimination systems. It also has helped to build up my general muscle tone.

c. *Applications.* The Stand-Alone has allowed me to remain erect while carrying on many other functions, such as answering the doorbell or telephone, preparing meals, reaching previously inaccessible closets, reading, and typing. I have used another Stand-Alone in an office. I find that I can conduct my organizational activities while standing, i.e., going to files, telephoning, dictating, bookkeeping, and running business machines.

d. *Psychological.* It has improved my mental outlook greatly by allowing me to perform the above-mentioned functions while in a standing position. It is a wonderful feeling not to be confined to a wheelchair any longer.

We quote from the evaluation report dated October 3, 1963:

a. From the very beginning, it was felt that the Stand-Alone would have a marked psychological effect upon the veteran. For the first time he would be able to stand for a considerable length of time (2–3 hours), move about in an upright position, work on a tray, which is attached to the device, while in the standing position, and move from room to room. Veteran reported there has been definite improvement in his bowel action. He finds it now easier to have a more complete and satisfactory evacuation. The evaluation would also determine whether there were any medical benefits derived from the device such as diminishing any tendency to genitourinary infections, progressive demineralization of the long bones, interruption of muscular spasm with greater ease and diminution of tendency to development of decubiti, especially in the region of the buttocks. Patient reported that since he has been using the Stand-Alone he has found that he can interrupt spasms of lower extremities with greater ease and that the frequency of recurrence of spasms has diminished.

b. G.U. evaluation of 9/13/63 discloses that patient is suffering from a neurogenic hypotensive bladder chronic and pyelonephritis with a moderate urinary residual. This is not unusual for this patient. It has been present for a number of years, and of interest is the fact that urinary residual has diminished from approximately 100 to 50 cc. On September 13, 1963, extensive X-ray evaluation of patient's long bones was made. The findings were "both legs show longitudinal striations at the end of the bone as well as other trabeculae going in other directions. There is . . . osseous density in the lower portion . . . representing the results of an *old* injury. There is also . . . local osteoporosis of the tibia. Both femurs show similar findings which could be due to osteoporosis." It was felt that these findings are not of recent origin and probably have been present for a considerable time.

c. Although the patient shows evidence of G.U. involvement and bony changes which are the result of a long-standing paraplegic state, they are not unusual in paraplegics.

d. Of major importance is the marked improvement in the patient's emotional state since he has been making use of the Stand-Alone device. He stated during the interview that to be able to get about in the upright position is something that he had never thought he would be able to do. He now has complete freedom of use of his upper extremities. Veteran

also finds that considerable less energy is required in getting about with the Stand-Alone when compared to navigation with the use of his braces. Of interest is the fact that there has been considerably less wear and tear of his clothes, which would frequently need attention as a result of the use of his braces. He finds that he is now able to "stand up" to his family and friends. Psychologically this is an extremely important reaction on the part of the patient.

e. It is the unanimous opinion of the board that if the Stand-Alone device was issued on a permanent basis to the veteran, that he would benefit to a considerable degree both psychologically and physically. The board further feels that no further useful information could be gained by continued followup of the above patient. If further evaluation of the Stand-Alone device was to be considered, it would be advisable that this be done with another patient.

EVALUATION SUMMARY OF VA HOSPITAL, CORAL GABLES, FLA.

Background

Subject had been using the Stand-Alone device outside of a hospital setting for 6 months prior to May 1963. At that time it was decided to take advantage of the experience he had with the device and include such findings in our report. Accordingly, a Selection Record was prepared by the VA Hospital in Coral Gables, and the subject scheduled for 1-month and 3-month followups. These were accomplished on June 28, 1963, and September 30, 1963, and the appropriate reports submitted.

The Subject

Subject is a 39-year-old veteran. He has a master's degree and is employed as a high-school teacher; he lives in a "special" house with ramps, and engages in shop work and swimming as hobbies. He is 6 ft. tall (weight not indicated), drives a car, using hand controls, and has assistance available at home.

His disability is shown as "traumatic paraplegia, level T3." He has no abdominal muscle power, and has limitation of motion of the right wrist. Before using the Stand-Alone, he reports that he would stand at home once a month for an hour, using braces and parallel bars.

Summary of Final Followup Report

Subject's Report. On September 30, 1963, a CAS 2–2 final Followup Report was submitted by the Chief, Physical Medicine and Rehabilitation. Subject reported that he was using the Stand-Alone 6 or 7 days a week, once or twice a day for an average of 2 hours at each session, standing the entire time. He rarely sat in the Stand-Alone, typically going from wheelchair to Stand-Alone, standing, and then back to wheelchair. He preferred the wheelchair for sitting because of its back support. He was able to get into and leave the Stand-Alone without assistance, by placing his feet in first, sliding onto the seat, grasping the top bars with his hands, standing

up, and then securing himself. He reported no difficulty obtaining a firm, upright position without assistance.

No irritation, soreness, or injury resulted from his use of the device.

Subject reported a psychologically much-improved attitude. He was now able to reach objects or perform hand functions above 4 feet from the ground, especially teaching at the blackboard. Its use made him more independent inside the house although he also used the device on sidewalks around the neighborhood without any reported difficulty. He found it easy to maneuver, stable in all directions, and less fatiguing than a wheelchair. He was confident and comfortable when using the device. As one would expect, he liked it.

Physician's Comments. Physician concurred with the benefits reported by the subject. He noted no bouts of urinary infection and less urinary sediment. He would prescribe the Stand-Alone selectively for cases of paraplegia of thoracic level. Curbs and slanted surfaces should be avoided. Training in entering and leaving the device was indicated. Optimum utilization of the device would be indicated on a part-time basis by paraplegics with residual arm and hand function.

Physician indicated that by using the Stand-Alone, braces could be eliminated, and possibly spare wheelchairs, standing frames, or tilting tables.

The doctor also stated that he was not sure, but that he doubted whether the Stand-Alone would be practical for cervical lesions, especially C5 and above. He did not think the device necessary for lumbar or cauda-equina lesions.

CONCLUSIONS AND RECOMMENDATIONS

Advantages of Stand-Alone

When selectively prescribed and effectively utilized, the Stand-Alone Therapeutic Aid can be a useful device in the medical management of individuals with loss of use of both lower extremities. The device should be utilized only when the disabled individual is ready to assume the upright position.

For suitable subjects, the use of the Stand-Alone makes possible the following advantages:

1. Mobility while standing;
2. Performance of meaningful tasks while in a standing position;
3. Exercise of shoulder girdle, arm, and hand;
4. Access to objects or places normally beyond reach in a sitting position;
5. Physiological benefits resulting from standing;
6. Psychological benefits derived from achieving the upright position and functioning in it; stimulation of interest in participating in a standing program.

The Stand-Alone is not considered a replacement for the aids and equip-

ment commonly used to help individuals develop a tolerance for the erect position, although it may serve as a useful supplement to the hospital therapeutic armamentarium after a patient has achieved readiness for standing. In such cases it is particularly helpful in that the expenditure of staff time can be minimized while patients are deriving benefits from the Stand-Alone.

Contraindications, Precautions, and Functional Requirements

Contraindications. The Stand-Alone is generally contraindicated in situations where:

1. Subject cannot maintain himself in the upright position without deleterious, hypotensive effect;
2. Breathing difficulties develop;
3. There are skin lesions at the pressure support areas; excessive pressures should be avoided;
4. The lower extremities are deformed;
5. The individual's residual upper-extremity function does not permit him to operate the device.

Precautions. The following precautions should be observed:

1. Sloping terrain may cause a lateral tilt of the device.
2. Although the device has been found to be stable in all planes, caution is required on uneven surfaces, inclines, ramps, curves, and waxed floors; this is particularly important for individuals with some limitation of the upper extremities.
3. Feet should be positioned properly in the device to allow good leverage in assuming the upright position.
4. The standing position should be comfortable.
5. Ascending and descending curbs should be avoided.

Functional Requirements. A minimum force of approximately 2 lb. is required at the drive wheels to set the device in motion on a hard, smooth, level surface; therefore, the user should be capable of generating at least 3 to 4 pounds of force in order to achieve mobility. Any pattern of muscle function which produces the required force at the drive wheels is suitable.

There is a close relationship between the level of lesion and the ease of utilization of the Stand-Alone device. Obviously, the lower the level of lesion, the greater the residual function and, therefore, the greater facility the individual will have with the device. Individuals with lesions at level T8 or higher will probably require assistance in entering and leaving the device. Adequate control in the movement of the presently-designed device requires a reasonably equivalent degree of muscular strength and motion in both upper extremities.

Training

It is essential that training be given the prospective user in entering and leaving the device and adjusting himself in it in a firm, upright position.

The manufacturer's manual should be revised in line with our previously submitted suggestions. It would be helpful if the manufacturer could provide copies of an effective instructional film.

The Stand-Alone does not provide the same benefits as those accruing from walking. Its availability should therefore not be used as a deterrent to any training program or walking regimen in which disabled individuals engage by combinations of use of braces, crutches, canes, and parallel bars.

Procurement and Issuance

A centralized system of procuring the Stand-Alone should be considered, to take advantage of reduced unit costs for quantity purchases and to provide a system of inspection and quality control.

The Stand-Alone should be furnished on a loan basis for a trial period to determine whether the disabled beneficiary can utilize the device. Such a trial period would also be a check on requests for the device based on its novelty, with subsequent rejection; this occurred several times in the field test. Wherever possible, clinical followup procedures should be undertaken to determine improvement, if any, in the user's condition.

Replacement of Other Devices

The Stand-Alone does not replace the wheelchair as the most usual means of affording mobility to individuals with loss of lower-extremity function. It cannot replace the basic wheelchair nor, for that matter, can the Stand-Alone substitute for spare wheelchairs that are necessary during intervals when the regular wheelchair is being repaired. It should also be noted that the user of a wheelchair can reach objects and places that are below reach in a Stand-Alone device.

In certain instances, furnishing of the Stand-Alone may eliminate the need to issue such items as spare braces, standing frames, tilt tables, and parallel bars.

The recommendation that the Stand-Alone can replace the need for spare braces is based on the rather common knowledge that many beneficiaries do not use any of the sets of braces furnished them. One could also anticipate a reduction in the number of brace repairs as well as in the number of new appliances issued.

If the Stand-Alone device is furnished only to beneficiaries who have demonstrated a readiness to stand, there is no need for standing frames and tilt tables.

It is recognized that some braced individuals use parallel bars for walking. This is physiologically and psychologically helpful; however, in those instances where no such walking regimen is carried on, the use of the Stand-Alone can eliminate the need for parallel bars.

Recommendations for Improving the Device

1. Consideration should be given to redesign of the seat attachment. It is suggested that replacing one pin with a spring-loaded latch would permit the patient to position it when standing. The distance between seat and knee support often proved insufficient to allow comfortable sitting, and some thought should be given to a method of eliminating this deficiency. It may be possible to raise the level of the seat so that the patient would not be sitting as low as he now does. Provision of a wider, approximately 14-inch band to act as a back support would make the sitting position more satisfactory. This is particularly important for individuals with trunk weakness.

2. Repositioning the detent pins horizontally may relieve discomfort when the patient's arms are pressed against the frame.

3. Although not of major significance, some redesign of the foot-fastening mechanism may be indicated for individuals with high lesions.

4. Several subjects suggested that the chest support be provided with a tilting mechanism similar to that used for the back support. It was also suggested that the thumbscrew method of securing the chest and back support could be replaced by a better method.

5. A wheel with eight spokes rather than the present four spokes would facilitate use for patients with arm involvements. Horizontal knobs or projecting bars would be helpful for some individuals with hand pathology. Possibly, these modifications could be made available on special order.

6. A one-arm drive model should be considered, utilizing the present wheel or a lever arrangement. Variable gear ratios would be of help where a subject has a marked difference in strength in the upper extremities. A triple gear on each side would be sufficient for most cases. Redesign of the pan supports to permit raising the pan for short individuals might be considered. This would place them in a more advantageous position to operate the drive wheels.

7. Almost all of the patients who used the Stand-Alone during the course of the field test experienced difficulties with the pins that are used to secure the front support and the backrests in position. Suggestions were made that the manufacturer improve this feature. Similarly, the locking mechanism was criticized as being inadequate in terms of design and location. These recommendations were made prior to the field test, and revisions have already been made.

8. Consideration should be given by the manufacturer to accommodate tall individuals and heavy individuals. The taller individuals (6 ft. 2 in. and over) had difficulty reaching the drive wheels; the heavier subjects complained that they were cramped in the device.

CURRENT POLICY

Based upon the findings of this report, the Veterans Administration approved the Stand-Alone as a device to be furnished under certain conditions to eligible veterans. Its use in VA hospitals and outpatient clinics was also approved. Circular 10–64–152, issued by VA's Department of Medicine and Surgery, outlines the procedures to be used for procurement and issuance of the device. When approval is obtained for the furnishing of the Stand-Alone to an eligible veteran, it will be lent to him for a minimum period of 6 months. If at the end of the first loan period, it is determined that the patient still needs the device and that he is obtaining therapeutic value from its use, the loan may be renewed for an additional period of 6 months. After one full year of use the device may be dropped from the loan status and permanently issued to the patient, if he still requires it.

REFERENCES

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