PART 2 TECHNICAL EVALUATION IN FIELD TESTING

by

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2.1 Introduction

Presently in Japan, design and manufacture of powered prosthetic arms are carried out by each designer on a case-by-case basis, with the designer making discretionary judgments of the various working conditions of the user based on the requests made from the medical side. Accordingly, there is the danger of some necessary points not being taken into consideration, thus making it hard to produce an ideal prosthetic arm. It is important, therefore, to investigate thoroughly how prosthetic arms are being used, to make objective evaluations of their performance and to establish guides for design, manufacture and evaluation, aiming at developing even better prosthetic arms in the future.

From such a point of view, this paper describes 1) what kind of performance a powered prosthetic arm is expected to exhibit, and 2) how the performance is to be evaluated in terms of engineering, based on the opinions gathered from the physically handicapped people as well as from people in the medical, social studies and engineering fields. The paper, at the same time, aims at providing the designer with referencial data concerning "what kind of matters he should take into consideration" in design.

2.2 Outline of a technical evaluation of powered prosthetic arms

Considerations to be taken in association with the technical evaluation of the powered prosthetic arms should include those articles described below.

(1) Is design excellent ?

Evaluation is made by comparing realized items with required items. The required items will vary in genera [illegible] person to person depending on the personal standpoint. Thus, as many items as possible should be taken into consideration, with degrees of priority given to the items in some cases. Such consideration is essential in order to design a useful prosthetic arm and will constitute a decisive factor in determining the quality.

(2) Is the result of production what is intended by the designer ?

No matter how well the designer may have designed the arm, giving full play to the quality and performance, the production of a useful prosthetic arm would be impossible unless the manufacturer properly understands what the designer intends and carries out the exact intention in manufacture. Thus, it is necessary to check whether this has been the case or not. For this reason, test and inspection are carried out with respect to the specifications.

(3) How high is the product quality ?

Generally, when experience in manufacturing the product is still short, it will be difficult to predict every performance at the stage of design. Therefore, limit test is carried out to know the limit to which the product can be used. This test is also necessary for confirming the performance of products whose performance is predictable.

The results of the test will be immediately fed back to design to enable improvement of performance , and also will be used as data for specifications to make the inspection items perfect.

(4) Other general items

(a) Object of evaluation

In addition, it is necessary to define whether checking is to be performed for the components that make up the product or for the overall product. In some cases, it may be preferable to disassemble the product to the components. But if there is time restriction in carrying out the test and inspection, it would seem reasonable to use the measured values obtained by the manufacturer as reference and confine evaluation to the overall products alone.

This method was adopted for the present test of the WIME HAND so that no test for disassembled components was carried out.

(b) How is evaluation to be made ?

Currently in Japan, design and evaluation of prosthetic arms are carried out based on the discretionary judgment of the individual undertaking the job. We believe, however, that the need is urgent to establish evaluation codes by defining the design guides, test and inspection methods, considering the Japanese mode of living and examples of actual applications of the prosthetic arms in foreign countries. Evaluation should be made based on these codes.

Due to the still poor reserves of testing data, the present field test for the WIME HAND fell short of being truly satisfactory. As will be explained later, test codes were drawn up and were used as the basis for carrying out tests and inspections.

(c) When is evaluation to be made?

Although evaluation of product quality including performance is carried out when the product is completed, it also should be made at fixed intervals during the period of use, and upon completion of use.

In the present test of the WIME HAND, in addition to the test at its completed stage carried out in accordance with the detail Machine Test Code, field test based on the simplified Machine Test Code (a simplified method adopted for the sake of reducing the trouble of the invalids who cooperated in the test) was carried out on a largely logarithmic schedule at intervals of 1 week, 2 weeks, 3 weeks, 6 weeks, 1 year and 2 years as described in Part I.

(d) Where is test to be done?

Due to the various instruments required for test and inspection, the places of tests will be confined to such places as workshops, physically handicapped people's centers and laboratories.

The present WIME HAND field test was carried out at the locations as described in Part I.

(e) By whom is evaluation to be done?

It is essential that evaluation be carried out in a total manner using judgment criterian that have been established based on the opinions gatherd from all persons concerned, including those of the medical side, engineering side and the invalids themselves. The present evaluation for the WIME HAND was carried out by the members of the "Committee for the Promotion of Practical Application of WIME HAND", a committee organized with persons associated with the WIME HAND as those described in Part I.

2.3 Criteria for technical evaluation

2.3.1 Evaluation relating to design techniques

Evaluation of design techniques should be carried out for the various items shown below.

(1) Configuration, dimensions and construction

- Are the required functions incorporated in the least space in a balanced compact manner, giving proper consideration to the position of the center of gravity? Does the construction allow ease of engineering work for repair?
- When a glove is fitted on the powered prosthetic arm to simulate the operating condition, does it resemble a human hand, being free of any unnatural protrusion?
- Is the size proper when such factors as sex and age are considered?
- Are the bending angles of the joints adequate?
- Is there any lack of naturalness in the bending condition of the joints?

- Is the speed of each finger movement proper?
- Is the set value of the pinching force proper?
- Is the set value of the gripping force proper?
- Is the set value of the grasping force proper?
- Is the set value of the lifting force of the finger except the thumb proper?
- Are the construction, configuration and dimensions of the wrist part adequate?
- Are the construction, configuration and dimensions of the myoelectric amplifiers and processor adequate?
- Are the construction, configuration and dimensions of the myoelecrtic electrodes adequate?
- Are the type, configuration and dimensions of the batteries (with case) adequate?
- Are the lengths and sizes of the cords connecting the myoelectric electrodes, myoelectric amplifiers, processor and powered prosthetic arm proper?
- Are the construction, configuration and dimensions of the connectors adequate?

(2) Parts arrangement
- Are the components of the powered prosthetic arm properly arranged?
- Are the myoelectric amplifiers and processor properly positioned?
- Is the position of the batteries adequate (for application in cold northern areas)?
- Are the switches adequately arranged?
- Are the connectors adequately arranged?

(3) Weight
- Into how light a package has the required function been incorporated?
- Are the mechanical parts of the powered prosthetic arm of an adequate weight?
- Are the batteries of an adequate weight?
- Are the myoelectric amplifiers and processor of adequate weight?

(4) Functions
- Of the functions possessed by man, what kind of functions are reproduced and to what extent? (The type of functions to be reproduced will be added in the order of those of the highest degree of importance to the lowest. This determination will depend on what purpose the powered prosthetic arm is to be used for.)

(5) Operating properties
- Is the design such that will not impose any mental or physical burden on the user during operation?
- Do the operating switches and emergency stop switch allow easy operation?

(6) Environment
- Has consideration been given to adaptability toward changes in the environmental conditions during application?
- Regarding high-temperature outdoor applications during summer, is the hand designed so that the functions of the myoelectric amplifiers and processor will be given full play?
- Regarding applications in cold northern districts in winter, are the myoelectric amplifiers and processor designed so that their functions

will be given full play?

- Regarding applications in cold northern areas in winter, are the batteries designed so that their functions will be given full play?
- Is the prosthetic arm designed so that its functions will be given full play in high-temperature, high-humidity conditions such as while walking in the rain in summer, or when washing dishes?
- Is consideration given to vibrations as will be experienced while driving a car, or while doing do-it-yourself carpentry?
- Is it designed so as to be free of erroneous operations even under strong electrical or magnetic fields (for example, around a television set, in a train, or near construction machines)?
- Is it designed to a dustproof construction?
- Are corrosion-resistive materials used?
- Are proper counter-measures taken to prevent the equipment from being seriuosly affected in case the rubber glove is torn during application under severe environmental conditions?

(7) Fitting properties

- Does the construction permit easy fitting and removal?
- Is fitting sure?

NOTE: For evaluation based on unnatural sensation and degree of fatigue, refer to the following chapters.

(8) Battery life

- Is the battery life (based on the total times of charging) adequate?
- Has the battery capacity been selected to a proper one?

(9) Maintenance

- Does the construction permit ease of maintenance?
- Are the parts required for maintenance easily available?
- Are standard parts used?
- Is lubrication adequate?
- Is it easily put away when it is not used (such as during the night) and easily taken out?
- Does the Operator's Manual describe in detail precautions concerning application?

(10) Interchangeability

- Are standard parts used for the components?
- Are the components designed with interchangeability taken into consideration?

(11) Safety factor

- In case of a failure, is the arm designed to fall on the safe side?
- When a load exceeding that prescribed is applied:
  - (a) Will some kind of alarm be sent out?
  - (b) Will it cause damage?
  - (c) Will it cause annoyance to the user or to other people?
    (In the case of hydraulic driving, will it cause such trouble as the oil spilling out over another person's clothes or body, when the piping has been damaged?)
- If the powered prosthetic arm catches fire, will it generate any toxic gas?
- Are the myoelectric electrodes and other electric sections designed so that no disaster will be caused to the human body?

(12) Life
- Is setting of the span of life adequate?

(13) Reliability
- Is the arm designed so as to minimize the failure rate?

(14) Noise
- Is it designed so as to ensure minimal noise generation during operation?
- Is the soundproof construction effectively functioning?

(15) Cosmetic properties
- Is it designed to give satisfaction to the wearer in terms of external appearance, configuration, dimension and color?
- Are measures taken against discoloration with time?

(16) Others
- Is the arm provided with resistivity and safety to protect it against abnormal use?

2.3.2 Detail machine test code

In order to draw up testing and inspection standards to evaluate the quality and performance of the myoelectric prosthetic arm in detail, the WIME HAND was taken up as one example, and its test code was drawn up.

2.3.3 Simplified machine test code

In order to draw up test and inspection standards to investigate the performance of myoelectric prosthetic arms by a simplified method on occasion during field test, the WIME HAND was taken up as one example, and its test code was drawn up.

2.4 Outline of practical example of technical evaluation

Described below in outline is the technical evaluation of WIME HAND, which was taken up as one example in the evaluation of the performance of myoelectric prosthetic arms.

As regards the WIME HAND that was taken up as the object of evaluation, there are three types: the 1st prototype manufactured during the period from April 1975 to the summer of 1976 and 2nd one made during the period from the summer of 1976 to that of 1977 and the final one manufactured from the autumn of 1977 onward. The 1st and 2nd prototypes were subjected to bench test and field test, whereas the final one were subjected only to bench test. As trial manufacture made progress from the 1st, 2nd on to the final, various improvements were made based on the results of previous tests.

As for the sites at which the tests and inspection were conducted, refer to part I.

Typical example of testing data are shown in Tables 2.1 through 2.5. Field test conducted for the 2nd prototype revealed the existence of such problems that call for:
- Improvement of perspiration-resistivity
- Reduction of the power source
- Decrease in backlash
- Reduction of noise
- Improvement of resistivity against external electro-magnetic noise

° Reduction of response time

To overcome such problem, the final prototype products were provided with a large number of countermeasures.

In the present investigation, evaluation of the man-machine system and psychological and social evaluation of the man system were carried out in addition to technical evaluation. Of them, evaluation made by the physically handicapped include those suggestions shown below.

(1) Concerning construction

- Lighter weight..........Heavy at the shoulder
- Water resistance........To prevent damage of glove
- External appearance.....Is rough and angular

(2) Concerning functions

- Higher opening and closing speed
- Improvement of shock resistance
- Improvement of reliability of movements
- Increase of the number of functions
- Larger gripping force
- Improvement of electro-magnetic noise resistance
- Reduction of noise

In addition to such evaluation , results of performance tests were obtained for the individual components. Also, the opinion of each user was obtained.

Overall technical evaluation was made for each evaluation items for the stated design techniques at the "Committee for the Promotion of Practical Application of WIME HAND" by a group consisting of the persons associated with the present field testing and academic authorities to judge the engineering level of the present electronic prosthetic arm as compared with the present prevailing scientific level. Details of the evaluation items and results of evaluation will be omitted here. The overall evaluation, however, was that "Although some points have yet to be improved, the technical level of the WIME HAND is above par".

2.5 Conclusion

(1) To establish the methods of the technical evaluation of the powered prosthetic arms, the design guide and test codes for checking specifications and performance of the prosthetic arms were drawn up, and the WIME HAND was taken up as the object of the evaluation as one example of the prosthetic arms.

(2) From results of the technical evaluation of the WIME HAND, these methods were assessed as useful for standards that will be established in the future. The field test of the WIME HAND presented many useful data. Since the world-wide accumulation of quantitative data is strongly desired, the WIME HAND has made a contribution to it

(3) As a result of such evaluation , the WIME HAND was assessed as having satisfactory performance for the present. However, in the future, improvement over improvement must be made to make it increasingly satisfactory, since it is the final target to approximate the great hand that man is endowed with.

Table 2.1 Weight of WIME HAND

prototype No. / component	1	2	3
hand(include wrist)	512	568	567
inner glove	1	1	3
cosmetic glove	75	114	97
wiring	21	21	20
electrodes (2 pieces,include spring)	48	48	50
battery	283	283	190
(sub total)	940	1035	927
electric stimulator	–	173	178
stimulative electrodes	–	15	13
(grand total)	940	1223	1118

(unit:g)

Table 2.2 Result of performance test of WIME HAND

performance			unit	prototype No. 1	2			3
			machine NO.	52	27	29	71	123
pinching functions	max. pinching force		kg	2.1	2.2	2.9	2.5	3.0
	pinching force		kg	2.0	2.2	2.5	2.3	2.5
	smallest object that can be pinched up	square rod □	mm	4	4	4	4	4
		round rod ∅	mm	5	5	5	5	5
		sphere ∅	mm	8	8	8	8	8
	largest object that can be pinched up ∅		mm	80	80	80	80	80
	max. weight that can be picked up (thickness:20 mm)		kg	1.3	2.5	2.5	2.5	3.0
	time	open--close	sec	1.1	1.1	1.1	1.1	1.2
		close--open	sec	1.0	1.1	1.1	1.1	1.2
gripping functions	max. gripping force		kg	2.8	2.6	2.9	2.5	4.5
	gripping force		kg	2.1	2.3	2.6	2.2	3.8
	max.cylinder dia. that can be gripped (pulling force:1kg)	pull axially	mm	30 -80	30 -80	30 -80	30 -80	80
		pull radially	mm	80	80	80	80	80
	security against pull (40 mm/20 kg)			OK	OK	OK	OK	OK
lifting functions	(20 kg)			OK	OK	OK	OK	OK
twisting function			kg.cm	7.7	8.2	7.7	10.0	8.7

Table 2.3 Noise of WIME HAND

prototype No.	1		2			3		
machine NO.	5	53	27	29	71	122	123	124
closing	63	59	61	56	62	56	53	61
opening	63	59	63	58	60	53	51	52

(unit: dB)
(distance:15 cm)

Table 2.4 Characteristics of myoelectric amplifiers of WIME HAND (prototype No. 3)

amplifier NO.			201	202	203
amp. gain (dB)		50 Hz	80.8	81.6	81.6
		550	89.5	89.8	90.4
		4000	80.0	80.0	80.8
output voltage (v)	input	20 µV	0.60	0.60	0.64
		40	1.3	1.3	1.3
		100	2.9	2.8	2.9
		200	3.2	3.1	3.2
current consumption (input terminal grounded)		mA	0.74	0.75	0.73
residual noise (gain max.)		mV	21	39	32

Table 2.5 Characteristics of myoelectric processor circuits, driving powercircuits and motor of WIME HAND
(prototype No. 3)

performance \ machine NO.		101	102	151
operating sensitivity (input level of 500 Hz sin.wave)				
start to close	V	1.43	1.47	1.41
stop closing	V	1.28	1.28	1.24
start to open	V	1.42	1.49	1.42
stop opening	V	1.24	1.30	1.25
response time(delay time)				
start to close	mS	61.6	69.7	61.8
stop closing	mS	54.4	65.4	68.8
start to open	mS	67.4	69.6	63.5
stop opening	mS	69.8	58.0	66.5
current consumption (fingers are moving)	mA	6.1	5.8	5.8
current limiter (operating current of limiter)	A	0.86	0.86	0.88