DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 1998

Ms. Karen Gotfredson
President
NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, Minnesota 55441

Re: K981730
Trade Name: Digit-Grip with LCD, Model DGR 002
Regulatory Class: II
Product Code: LBB
Dated: May 12, 1998
Received: May 15, 1998

Dear Ms. Gotfredson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981730

Device Name: Accessories for Digit-grip with LCD

Indications For Use: Model # 16K002

Karen Gayfield
President

INDICATIONS FOR USE: The ULTIMATE System is indicated for use as follows:

1. to measure grip or pinch strength in an injured and uninjured hand.
2. to follow an injury through the rehabilitation process and measure progress or lack of progress, in terms of grip or pinch strength, of the therapy regimen or medical treatment.
3. to document baseline grip or pinch strength of the hands and lifting, pulling and pushing strength capabilities of employees and to monitor the strength of employees in the work-place over time.
4. generally, in any situation where the hand grip or pinch strength would be a valuable piece of data in the evaluation of a person who has sustained an injury or suffers a disease to his/her hand(s).
5. to establish an industrial strength testing program in general, and to match the strength of workers to the strength demands of specific job duties in the workplace (lifting, pulling and pushing protocols) in a simulated test.
6. to conduct pre-employment screening for physically demanding job activities.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981730

Prescription Use___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 1998

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10850 Old County Road 15
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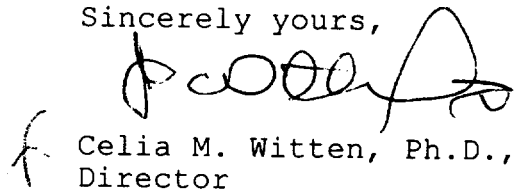
Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981730

Device Name: Accessories for Digit-grip with LCD

Indications For Use: Model # 16K002

Karen Garfieldson
President

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3. to document baseline grip or pinch strength of the hands and lifting, pulling and pushing strength capabilities of employees and to monitor the strength of employees in the work-place over time.
4. generally, in any situation where the hand grip or pinch strength would be a valuable piece of data in the evaluation of a person who has sustained an injury or suffers a disease to his/her hand(s).
5. to establish an industrial strength testing program in general, and to match the strength of workers to the strength demands of specific job duties in the workplace (lifting, pulling and pushing protocols) in a simulated test.
6. to conduct pre-employment screening for physically demanding job activities.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981730

Prescription Use___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) N. K. MISHRA

Subject: 510(k) Number K981730

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review_____.
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☐ YES	☑ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)?	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

- ☐ A 510(k) summary OR ☑ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☑ The indication for use form (required for originals received 1-1-96 and after)

☐ Animal Source Material ☐ Human Tissue Product ☐ Human Cell Product ☐ Human Extraction Product
(Please Check All That Apply)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: LZB / II / OR

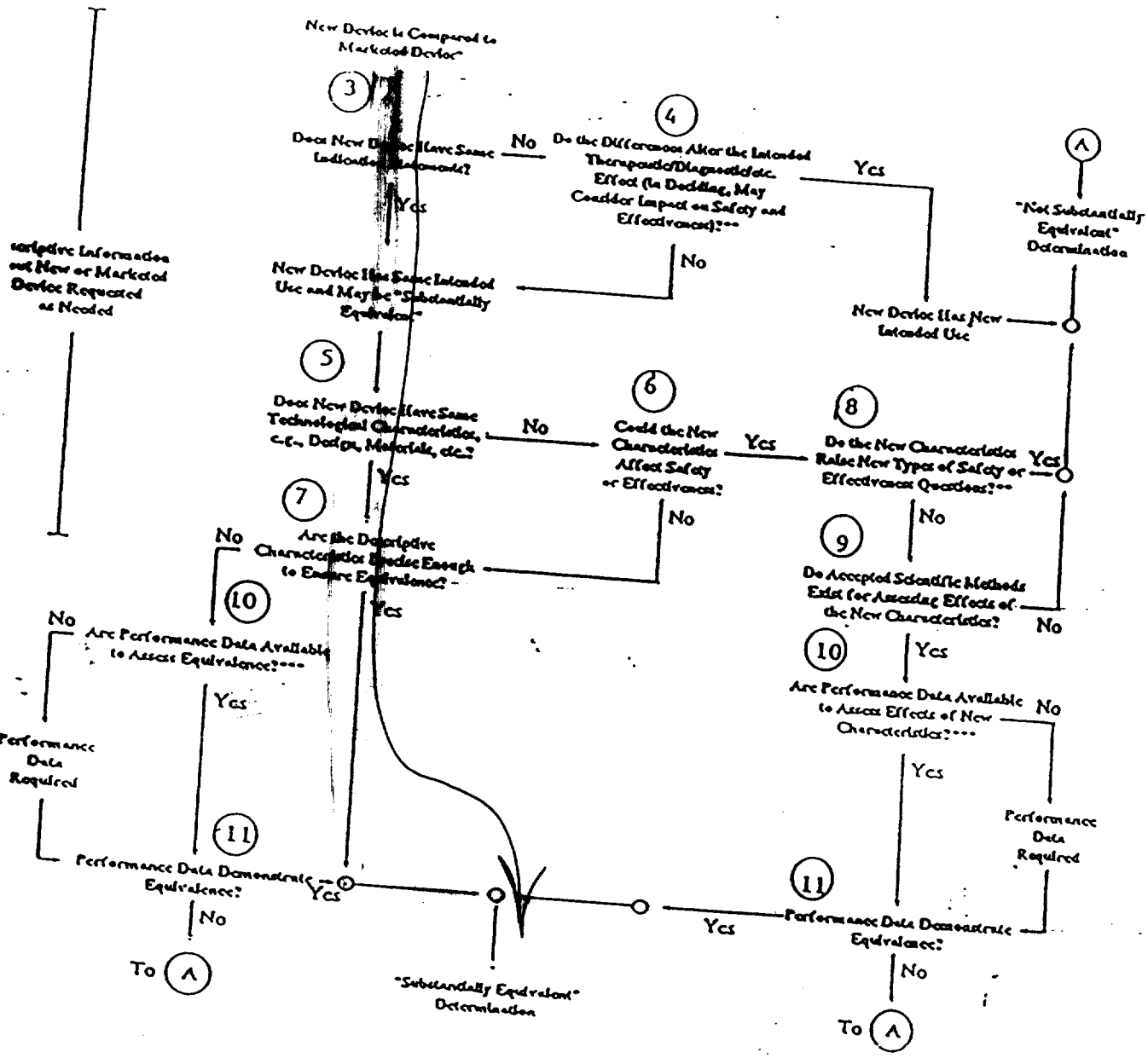
Additional Product Code(s) with panel (optional):

Reviewed by: Mark N. Milkerson (Branch Chief) ORDB (Branch Code) 7/10/98 (Date)

Final Review: (Division Director) 7/17/98 (Date)

Revised:2/19/98

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



10(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship etween marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

is decision is normally based on descriptive information alone, but limited testing information is sometimes required.

ta may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

This is a simple dynomometer for measuring Grip strength. If the measuring ~~need~~ indicator needle was mechenical; instead of battery operated this devied ~~will~~ would be exempt from 510(k).

7/8/98

7/8/98

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: Digi Grip Dynamometer							K981730
Submitter (Company):							
Items which should be included *(circle missing & needed information)*	SPECIAL		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,4		GO TO # 3,4,5		✓ GO TO # 4,5		
2. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							✓
b) ***STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED****			* If no - STOP not a special				✓
c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****			* If no - STOP not a special				✓
d) Design Control Activities Summary							
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis							
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied							
iii) A declaration of conformity with design controls. The declaration of conformity should include:							
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met							
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review							

→ → → CONTINUE TO SECTION 4 ← ← ←

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS	YES	NO	YES	NO	YES	NO	
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

→ → → CONTINUE TO SECTION 4 ← ← ←

4. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, address of manufacturer. device class					✓		
b) OR a statement that the device is not yet classified	FDA - may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*					✓		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:							
i) package labeling (user info)							
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)					✓		
m) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) labeling					✓		
ii) intended use					✓		
iii) physical characteristics					✓		
iv) anatomical sites of use					✓		
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
n) If kit, kit certification							
5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No** **Reviewer:** N.K. MISHRA

Date: _____ **Concurrence by Review Branch:** _____

K981730/A1

NK BIOTECHNICAL CORPORATION
"Aerospace and Medicine...Partners in Science"

10850 Old County Road 15
Minneapolis, MN 55441

Phone (612) 541-0411 FAX (612) 541-0863
USA Toll Free Phone (800) 462-3751
USA Toll Free (Voice & Text) Pager (800) 582-6614

E-mail: sales@nkb.com
Web site: www.nkb.com

May 27, 1998

Center for Device and Radiological Health
Food and Drug Administration
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: 510(K) NOTIFICATION: ACCESSORIES FOR THE NK DIGIT-GRIP SENSOR, MODEL DGR002 - NK ULTIMATE SYSTEM
AMENDMENT TO ORIGINAL SUBMISSION DATED MAY 12, 1998
510K No. K981730

Attention: Document Mail Clerk

Dear Sir/Madam:

We hereby amend our original submission letter as described above in the following manner:

Indications for Use as stated in the original submission are submitted again on the form prescribed by the FDA, which is attached hereto.

Thank you for your courtesies.

Sincerely yours,

Karen Gotfredson
President

K-29

KG/ml
Enclosures

510(k) Number (if known): K981730

Device Name: Accessories for Digit-grip with LCD

Indications For Use: Model # JGK002

Karen Gayfield Anderson
President

INDICATIONS FOR USE: The ULTIMATE System is indicated for use as follows:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 19, 1998

NK BIOTECHNICAL CORP.
10850 OLD COUNTY RD. 15
MINNEAPOLIS, MN 55441
ATTN: KAREN GOTFREDSON

510(k) Number: K981730
Received: 15-MAY-1998
Product: DIGIT-GRIP WITH LCD, MODEL NUMBER DGR 002

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

K981730

DIGIT–grip (Level 1)

and ULTIMATE SYSTEM Components

510k Submission to FDA

OR dass II

SK-35

NK Biotechnical Corporation
10850 Old County Road 15, Minneapolis, Minnesota 55441
Telephone: (612) 541–0411 Fax: (612) 541–0863

510K Submission to the FDA

DIGIT–grip with Attachments
(Ultimate Series)

NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, Minnesota 55441
Telephone: (612) 541–0411
Fax: (612) 541–0863
Toll Free: (800) 462–3751

COVER SHEET

SUBMITTAL LETTER

APPENDIX A

APPENDIX B

APPENDIX C

APPENDIX D

1h

510K Submission to the FDA

DIGIT–grip with Attachments (Ultimate Series)

COVER SHEET

NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, Minnesota 55441
Telephone: (612) 541–0411
Fax: (612) 541–0863
Toll Free: (800) 462–3751

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission:	FDA Document Number:

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission — 510(k)s Only

- ☐ New device
- ☒ Additional or expanded indications
- ☐ Change in technology, design, materials, or manufacturing process
- ☐ Other reason (specify):

Section B2 — Reason for Submission — PMAs Only

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Other (specify below)
- ☐ Process change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Response to FDA correspondence (specify below)
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment

Section B3 — Reason for Submission — IDEs Only

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☐ Additional information
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing
  - ☐ Protocol – feasibility
  - ☐ Protocol– other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

FDA Document Number:

Section C — Product Classification

Product code: 888.1250	C.F.R. Section:	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Dynamometer - grip strength tester		

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 888.1250	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 Exempt	1 JAMAR Dynamometer	1 Therapeutic Equip Co.
2 Exempt	2 Chatillon Strength Dynamometers	2 Chatillon Medical Dynamometers
3 Unknown	3 JTech Medical Strength Devices	3 JTech Medical
4	4	4
5	5	5
6	8	8

Section E — Product Information — Applicable to All Applications

Common or usual name or classification name:
Dynamometer

Trade or proprietary or model name	Model number
1 Digit-grip with LCD	1 DGR 002
2	2
3	3
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome):

1 K923963	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling):

FDA Document Number:

Section F — Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2183999	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name: NK Biotechnical Corporation

Division name (if applicable):	Phone number (include area code): (612) 541-0411
Street address: 10850 Old County Road 15	FAX number (include area code): (612) 541-0863

City	State / Province	Country	ZIP / Postal Code
Minneapolis	Minnesota	USA	55441

Contact name: Karen Gotfredson

Contact title: President

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name:

Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )

City	State / Province	Country	ZIP / Postal Code

Contact name:

Contact title:

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler

Company / Institution name:

Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )

City	State / Province	Country	ZIP / Postal Code

Contact name:

Contact title:

FDA Document Number:

Section G Applicant or Sponsor

Company / Institution name: NK BioTechnical Corporation	FDA establishment registration number: 2183999
Division name (if applicable):	Phone number (include area code): (612) 541-0411
Street address: 10850 old County Road 15	FAX number (include area code): (612) 541-0863

City: Minneapolis	State / Province: Minnesota	Country: USA	ZIP / Postal Code: 55441

Signature: Karen Gotfredson

Name: Karen Gotfredson

Title: President

Section H Submission correspondent (if different from above)

Company / Institution name:	
Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )

City:	State / Province:	Country:	ZIP / Postal Code:

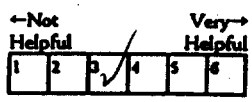
Contact name:

Contact title:

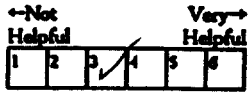
Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

Survey on Costs and Benefits of Premarket Submission Cover Sheet

1. Did use of the Premarket Submission Cover Sheet help you *organize* your submission?

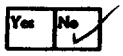


2. Did use of the Premarket Submission Cover Sheet help you prepare a *complete* submission?

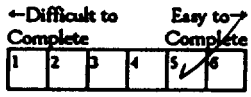


3. Is there any information requested by the Premarket Submission Cover Sheet that you believe is *unnecessary* or *inappropriate*? If "yes," please provide suggestions on items to remove, and why:

4. Is there any *additional* information you believe should be requested by the Premarket Submission Cover Sheet? If "yes," please provide your suggestions on items to add:



5. Overall, is the Premarket Submission Cover Sheet organized to make it easy to complete?



6. How can the Premarket Submission Cover Sheet be better organized to make it easier to complete?

FDA USE ONLY — Please do not write in this area.

Document number: _____

Data entry control: _____

17. May we contact you if we have questions concerning your responses to this survey? [X] Yes [ ] No

If "yes," please provide a phone number: 612-541-0411

18. If you have additional suggestions or comments, please provide them below.

Please include this survey with your premarket submission.
Send all materials to:

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

510K Submission to the FDA

DIGIT–grip with Attachments (Ultimate Series)

SUBMITTAL LETTER

NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, Minnesota 55441
Telephone: (612) 541–0411
Fax: (612) 541–0863
Toll Free: (800) 462–3751

NK BIOTECHNICAL CORPORATION
"Aerospace and Medicine...Partners in Science"

10850 Old County Road 15
Minneapolis, MN 55441
P.O. Box 26335, ~~Minneapolis, MN 55426~~
Phone (612) 541-0411 FAX (612) 541-0863
Toll Free (800) 462-3751

May 12, 1998

Center for Device and Radiological Health
Food and Drug Administration
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: 510(K) NOTIFICATION: ACCESSORIES FOR THE NK DIGIT-GRIP SENSOR, MODEL DGR002 - NK ULTIMATE SYSTEM

Attention: Document Mail Clerk

Dear Sir/Madam:

This is to notify you of the intention of **NK Biotechnical Corporation, formerly NK Biotechnical Engineering Company - FDA Establishment No. 2183999 - (NKB)**, to manufacture and market the accessories described herein for the NK DIGIT-grip Device with LCD Display (Model DGR002), which received 510K premarket clearance as a Class I device on May 2, 1997 (No. K970870).

The accessories for which premarket clearance is now requested are for the purpose of expanding the use of this device beyond the testing of hand grip strength, to include the ability to accurately measure push, pull and lift strength. The components are sold with the DIGIT-grip device as a custom system, configured from the following components, which are more completely described in Appendix A:

1.	Child's Grip Handle/Pinch Handle	(ULT001/ULT002)
2.	Additional Handle for Grip Device	(ULT003)
3.	Wide Flat Push Handle	(ULT004)
4.	Concave Push Handle Attachment	(ULT005)
5.	Palmar Handle Attachment	(ULT006)
6.	Hand (Half Grips) Handle Attachments	(ULT007)

7. 180° Adapter for use with LCD Display	(ULT008)
8. LCD Display Cable Extension	(ULT009)
9. Pull-Lift Assembly Cable	(ULT010)
10. Aluminum Footplate	(ULT011)
11. Custom Carrying Case	(ULT012)
12. T-Bar Assembly with Load Cell & LCD Display (500# Capacity)	(ULT013)
13. T-Bar Assembly for DIGIT-grip (220# Capacity)	(ULT014)
14. Totepan Assembly for DIGIT-grip (220# Capacity)	(ULT015)

SUBSTANTIAL EQUIVALENCE: The NK ULTIMATE System consisting of the DIGIT-grip device (Model DGR002) and components (Models ULT001 through ULT 015) submitted for premarketing clearance by this letter are substantially equivalent in function to the ***Chatillon Dynamometer Systems- Appendix B-1)*** that were marketed in USA interstate commerce prior to May 28, 1976 and remain on the market today. Further, they are substantially equivalent to two additional systems being marketed in interstate commerce today, being the ***Jackson Evaluation System (Lafayette Instruments)-Appendix B-2*** and ***JTech Medical Lifting and Job Analysis System - Appendix B-3.***

Appendix B, which includes product information on these three systems, also contains several published articles which describe the basis for the testing protocols provided by these systems.

NKB submits this 510(k) with the intent to demonstrate, via the documents included in the Appendices that its NK DIGIT-grip Device (Model DGR002), together with Components (Model ULT001-ULT015) have the same intended use as the above three described systems, being the measurement of lift, pull and push strength.

ACCURACY: The NK DIGIT-grip Device (Model DGR002) and the 500# Load Cell Component are calibrated in the NIST Traceable Metrology Laboratory maintained by NK Biotechnical Corporation. Documents describing the NIST Traceable Laboratory equipment, sample calibration certificate, the results of NKB'S last GMP inspection, as well as pertinent product warranties, specifications and labeling are included in Appendix C.

SAFETY AND EFFICACY: The Appendix C documents fully support our contention that the NK DIGIT-grip Device (Model DGR002) and ULTIMATE components (ULT001-ULT015) are at least as safe and effective as, and do not raise different questions regarding safety and effectiveness from, the predicate devices/systems.

PRODUCT MATERIALS: To provide specific instructions on this device's meaurement capability and how to operate it, Appendix D contains the complete Users Manual.

INDICATIONS FOR USE: The ULTIMATE System is indicated for use as follows:

1. to measure grip or pinch strength in an injured and uninjured hand.
2. to follow an injury through the rehabilitation process and measure progress or lack of progress, in terms of grip or pinch strength, of the therapy regimen or medical treatment.
3. to document baseline grip or pinch strength of the hands and lifting, pulling and pushing strength capabilities of employees and to monitor the strength of employees in the workplace over time.
4. generally, in any situation where the hand grip or pinch strength would be a valuable piece of data in the evaluation of a person who has sustained an injury or suffers a disease to his/her hand(s).
5. to establish an industrial strength testing program in general, and to match the strength of workers to the strength demands of specific job duties in the workplace (lifting, pulling and pushing protocols) in a simulated test.
6. to conduct pre-employment screening for physically demanding job activities.

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT: I certify that, in my capacity as President of NK Biotechnical Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate, and that no material fact has been omitted.

PREMARKET NOTIFICATION 510(k) STATEMENT (as Required by 21 CFR 807.93): I certify that, in my capacity as President of NK Biotechnical Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers and trade secret and confidential information, as defined in 21 CFR 20.61.

Thank you for your courtesies.

Sincerely yours,

Karen Gotfredson

Karen Gotfredson
President

KG/ml
Enclosures

510K Submission to the FDA

DIGIT–grip with Attachments (Ultimate Series)

APPENDIX A

NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, Minnesota 55441
Telephone: (612) 541–0411
Fax: (612) 541–0863
Toll Free: (800) 462–3751

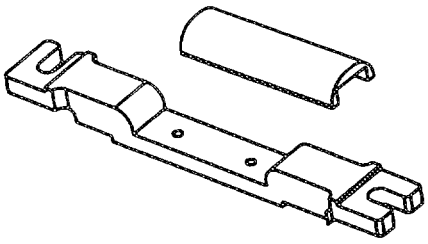
NK Biotechnical Corporation

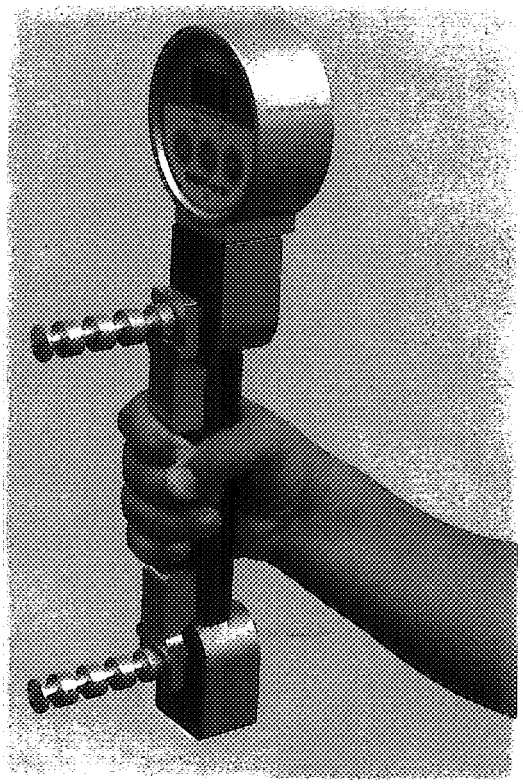
ULTIMATE SYSTEM COMPONENTS

Model No.	Product Description	Appendix Page No.
DGR002	DIGIT-grip with LCD Display and Battery Charging Cable	A-1
ULT001	Child's Grip Handle	A-1
ULT002	Pinch Handle	A-1
ULT003	Additional Handle (for Total 10 Grip Positions)	A-2
ULT004	Wide Flat Push Handle Attachment	A-3
ULT005	Concave Push Handle Attachment	A-4
ULT006	Palmar Handle Attachment	A-5
ULT007	Hand (Half Grips) Handle Attachments (Pair)	A-6
ULT008	180 Degree Adapter for use with DIGIT-grip with LCD Display	A-7
ULT009	LCD Display Cable Extension (for LCD remote from DIGIT-grip)	A-7
ULT010	Pull-Lift Assembly Cable (Standard Cable Length -28")	A-8
ULT011	Footplate (Aluminum)	A-9
ULT012	Custom Carrying Case	A-10
ULT013	T-Bar Assembly with Load Cell and LCD Display Readout (500# Capacity)	A-11
ULT014	T-Bar Assembly for DIGIT-grip (220# Capacity)	A-12
ULT015	Totepan Assembly for DIGIT-grip (220# Capacity)	A-13

ULT001
Child's Grip Handle

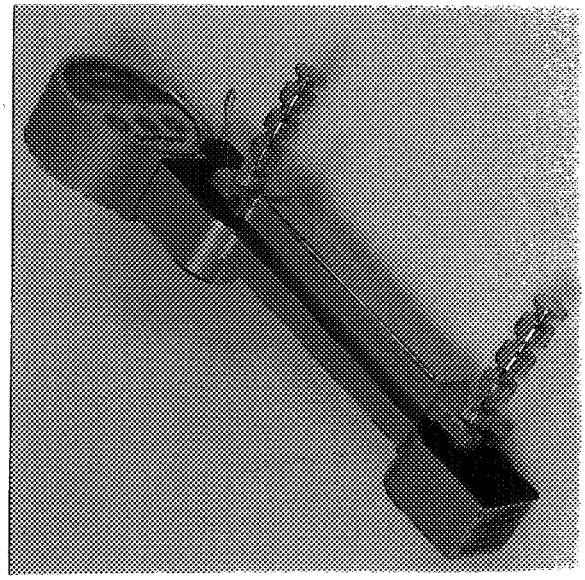
ULT002
Pinch Handle





This is the same Handle. When used to measure the grip strength of a child or adult with a small hand, the handle is used with the black plastic cover.

When used to measure pinch strength, the handle is used without the black plastic cover.



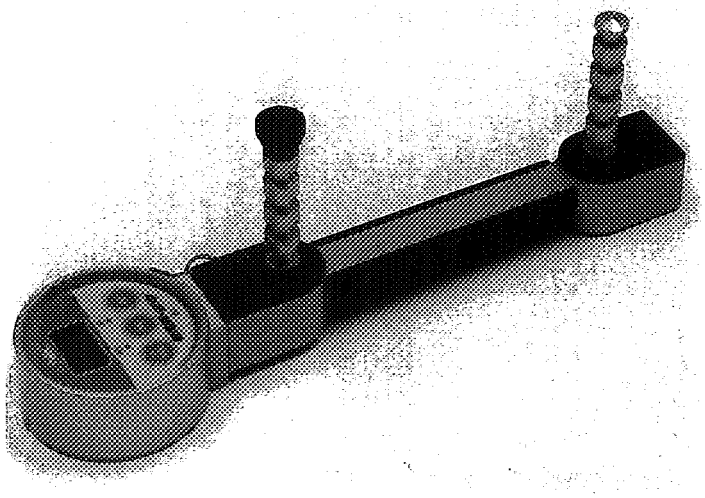
To use, remove the standard grip strength handle from the DIGIT–grip substitute this handle.

Appendix A–1

ULT003

Additional Handle

(allows an additional 5 Grip Positions to be used in testing.



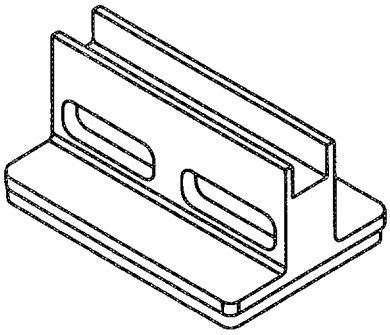
The posts of the DIGIT–grip body allow for the standard handle to be affixed in five different testing positions to accommodate hand size.

If the user wants to use more than the five standard positions – by using this handle in place of the standard one affixed to the back side of the DIGIT–grip body, effectively five additional positions are provided.

Appendix A–2

ULT004

Wide Flat Push Handle

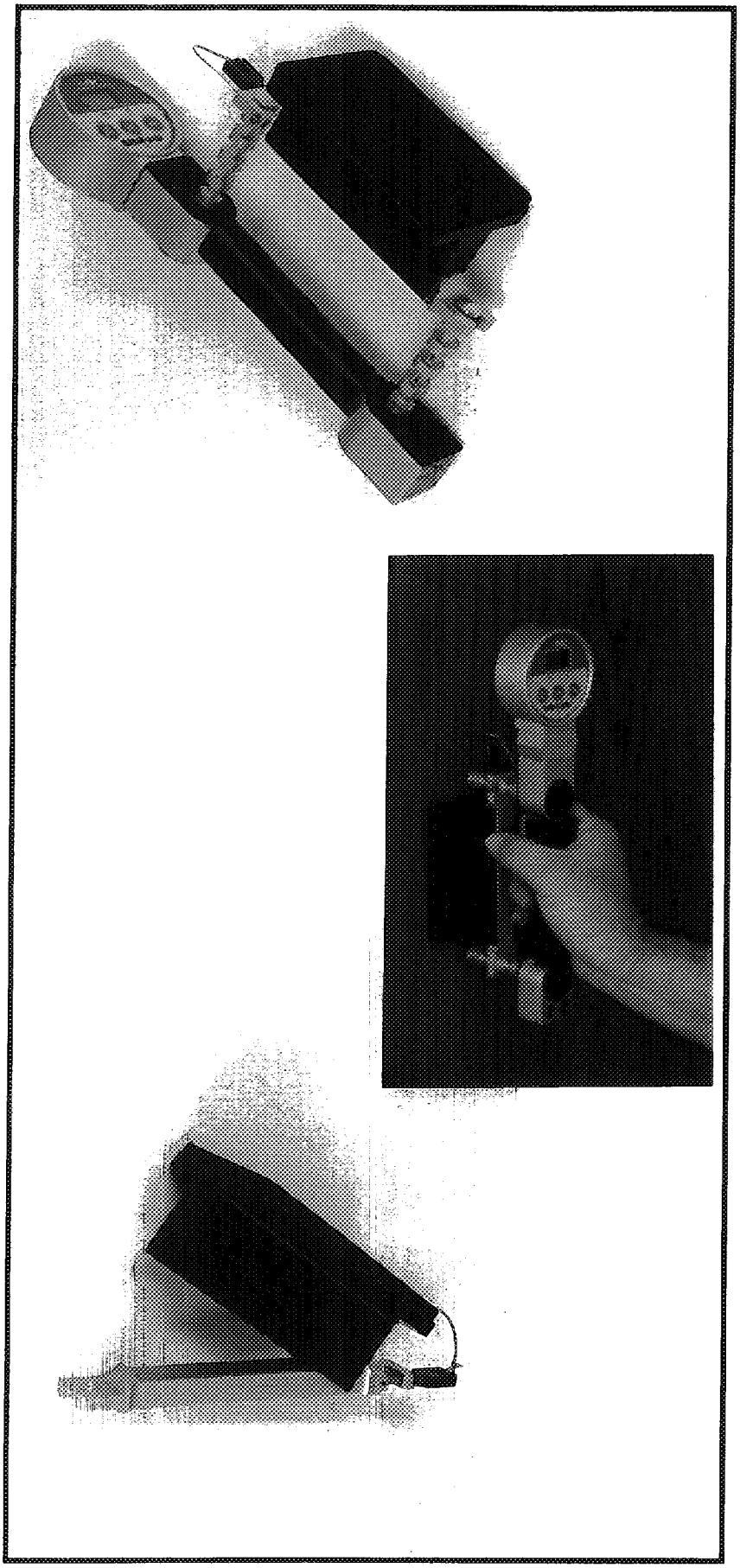


The Wide Flat Push Handle can be substituted for the standard grip handle to measure the push force in many test protocols, including:

measuring the peak force required to move any moveable object, such as a cart of supplies in the work–place.

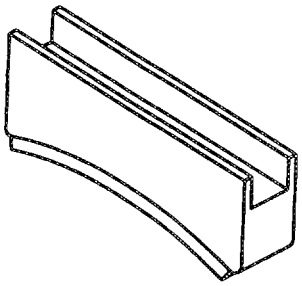
Push can be measured by pressing the handle to any fixed or moveable surface.

By using the 180 Degree Adapter (ULT009), the face of the LCD Display affixed to the DIGIT–grip device facing opposite its usual position to allow easy reading of the peak force numbers generated.

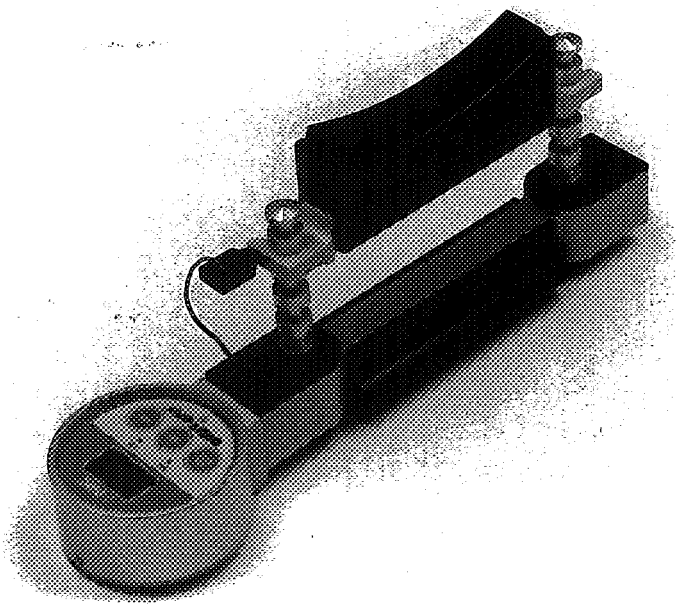


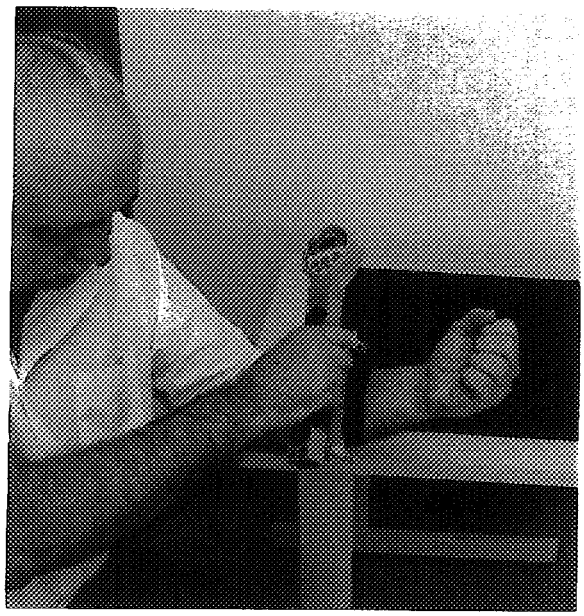
ULT005

Concave Push Handle



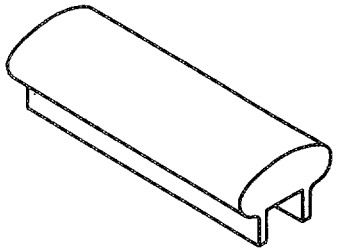
The Concave Push Handle can be substituted for the standard grip handle to measure the push force in test protocols that are best run using a concave handle, for example, testing force at the wrist.



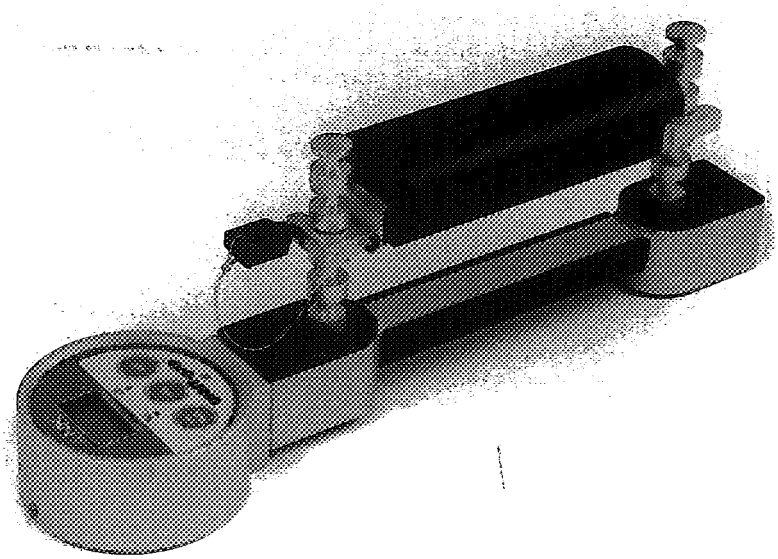


ULT006

Palmar Handle



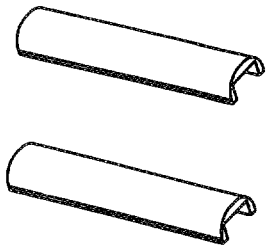
The Palmar Handle can be substituted for either of the standard grip handles for push and lift grip testing procedures.

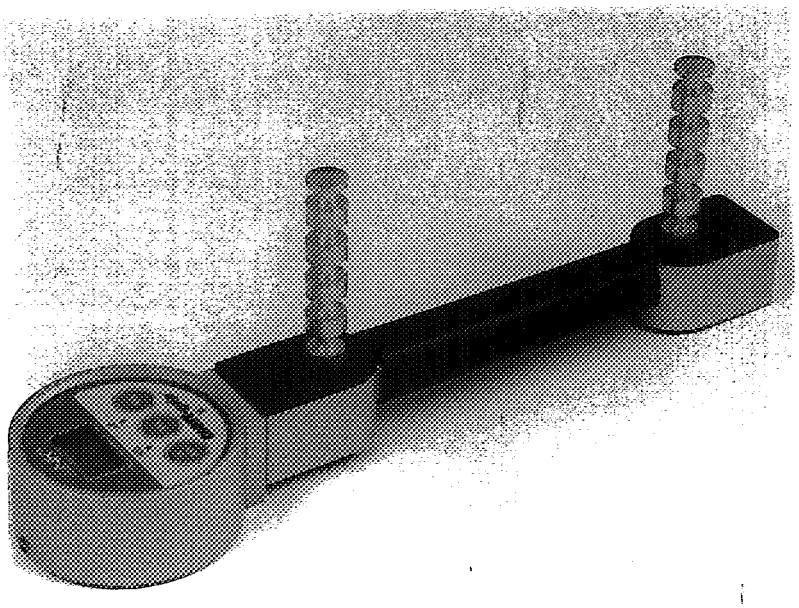


Appendix A–5

ULT007

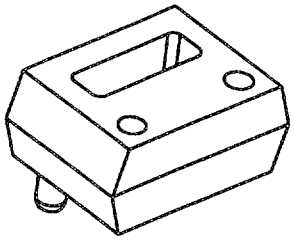
Hand (Half Grips)

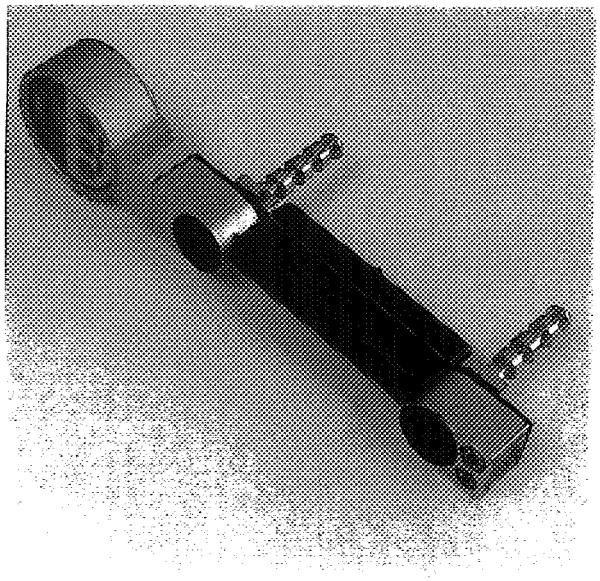




The Half Grips are substituted for the one standard grip handle that is affixed to the back of the DIGIT–grip body. The use of these Half Grips is recommended when doing any test protocol that requires the subject to apply a pulling force on the base (back) of the DIGIT–grip device.

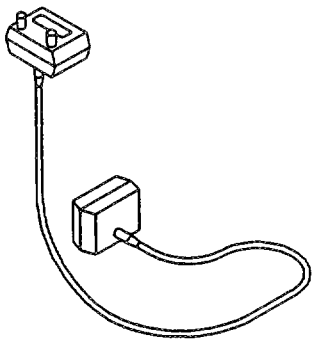
ULT008
LCD 180 Degree Adapter





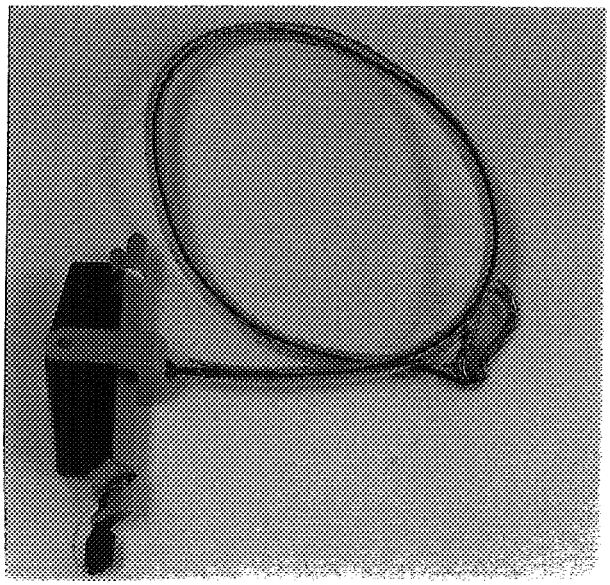
The LCD 180 Degree Adapter allows the LCD Display Face to be affixed to the DIGIT–grip body facing in the direction opposite from its standard configuration. This is useful to display test data in most push and lift test procedures.

ULT009
LCD Display Extension Cable

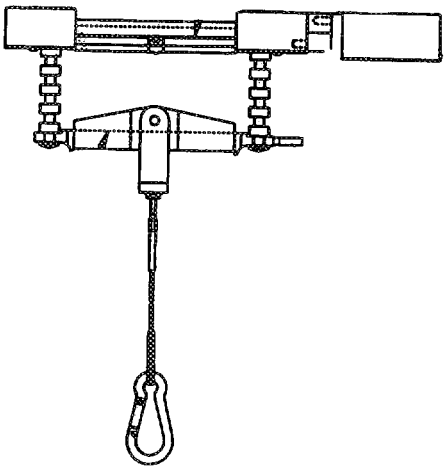


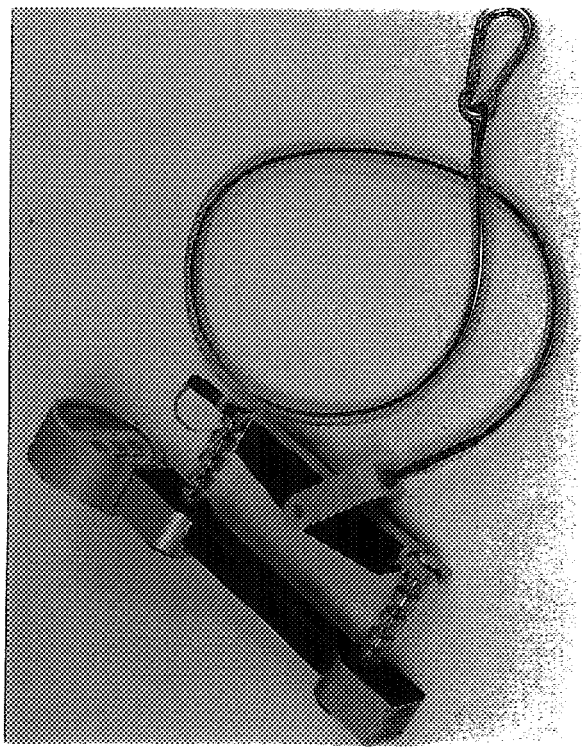
The LCD Display Extension Cable allows the use of the LCD Display remote from the DIGIT–grip Body by connecting the two components with a flexible interface cable.

ULT010
Pull-Lift Cable Assembly

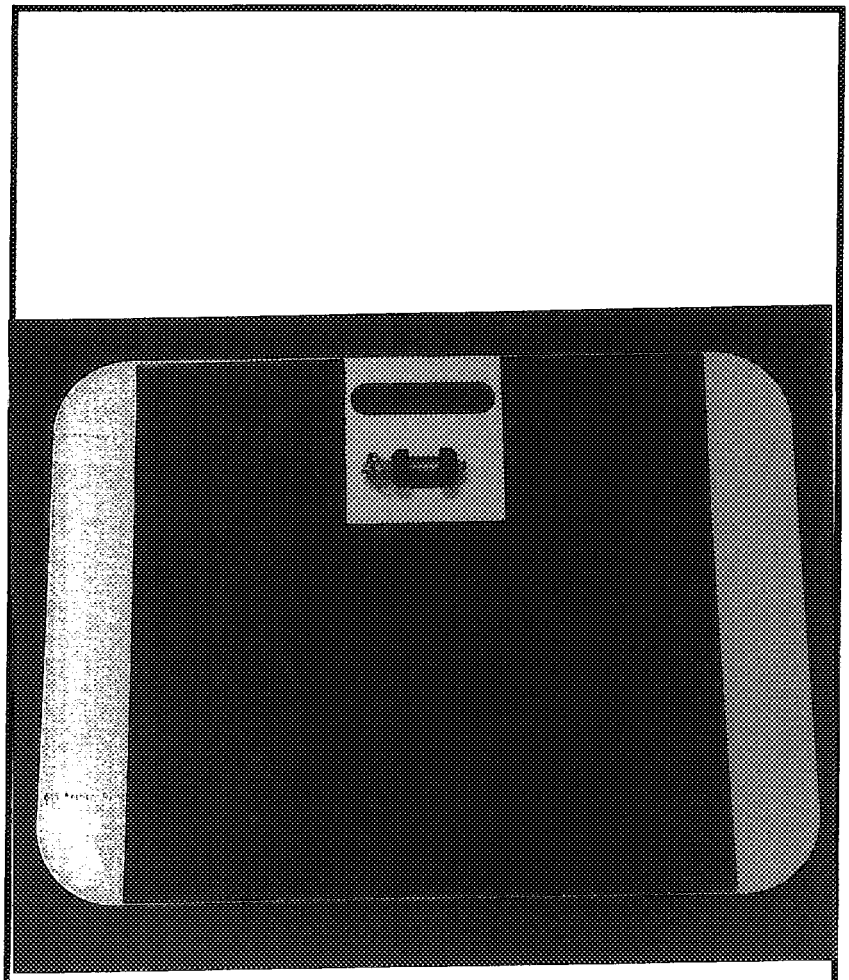


This attachment is used to perform pull and lift test procedures and can be used to test peak force necessary to move anything that moves, i.e. a loaded cart in the workplace.





ULT011
Footplate



This aluminum footplate with dimensions of:
23.5" width – 17.5" height
.5" deep

is used with the ULT Lift Assemblies:
ULT013, ULT014, ULT015, ULT016

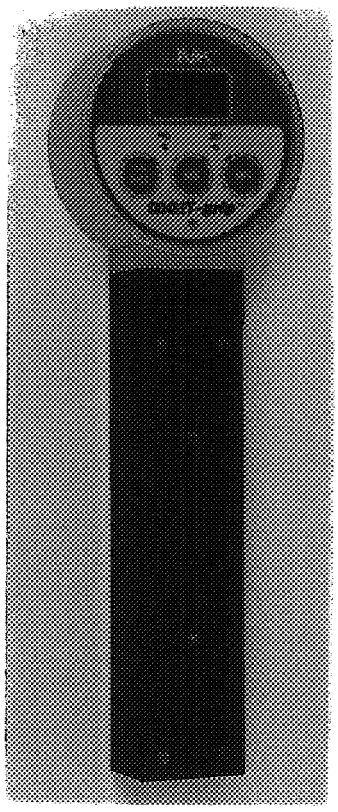
ULT–12
Custom Carrying Case

The Ultimate Systems are Modular and can be custom assembled to include only the components ordered. A custom case of the type shown here is provided with all ULTIMATE Systems.

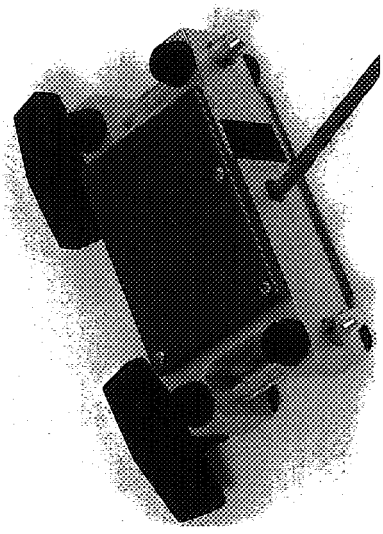
ULT013
T–Bar Assembly with NK Load Cell and LCD Readout (500# Capacity)

Assembly before attachment to Footplate

This Assembly is used for test protocols involving back and arm lifting strength.



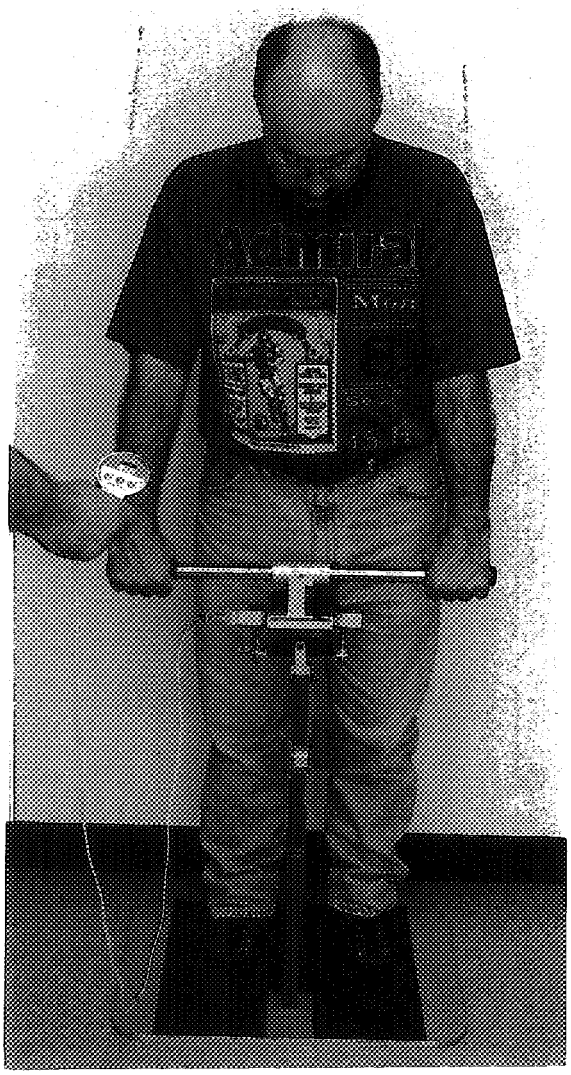
LCD Readout

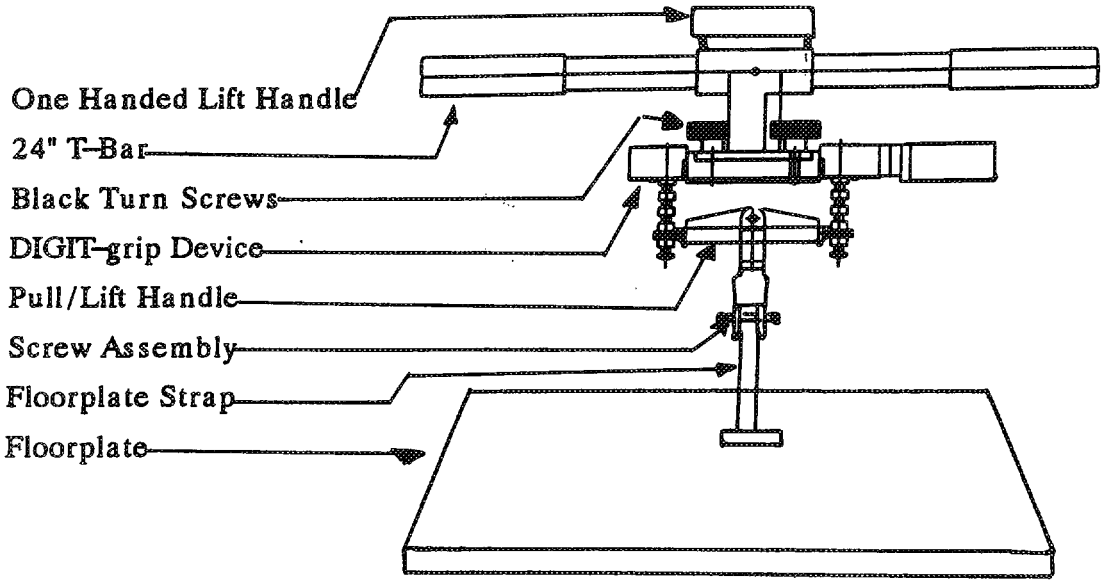


NK 500# Load Cell

ULT014
T–Bar Assembly with DIGIT–grip
(220# Capacity)

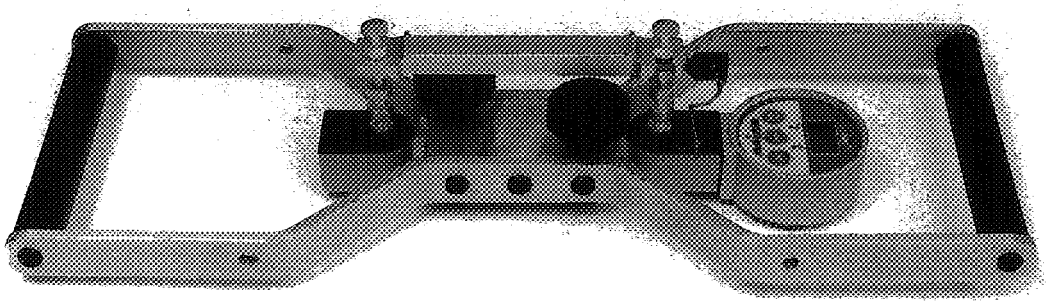
This Assembly is also used for test protocols involving back and arm strength.



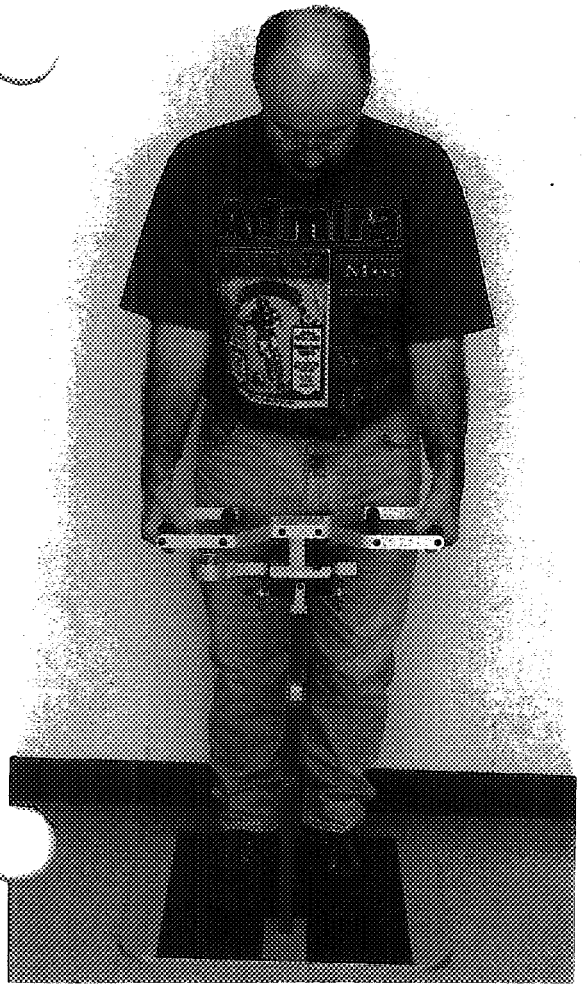


Appendix A–12

ULT015
Totepan Assembly with DIGIT–grip
(220# Capacity)



This Assembly is also used for test protocols involving back and arm strength.



510K Submission to the FDA

DIGIT–grip with Attachments (Ultimate Series)

APPENDIX B

NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, Minnesota 55441
Telephone: (612) 541–0411
Fax: (612) 541–0863
Toll Free: (800) 462–3751

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NK Biotechnical Corporation

ULTIMATE SYSTEM COMPONENTS

42

ONE HIGHLY RESPECTED NAME.

Since 1835, Chatillon has been one of the most trusted names in scales and force measurement instruments. For years clinicians have been using Chatillon dynamometers for a variety of force evaluations. Today, the expertise and experience gained during all those years are being applied to new state of the art medical dynamometers. The CSD line can provide you with measurement equipment that is easy to use, affordable and reliable. Chatillon Dynamometers provide you with the objective data that is required in the modern health care climate.

For more information call or write:

WARRANTY AND LIMITATION OF LIABILITY

Chatillon expressly warrants to its buyer for one year from the date of purchase that the goods sold shall be free from defects in workmanship and materials under normal conditions. Chatillon, at its option, will return the purchase price of repair or replace, without charge, any goods which it finds defective in either workmanship or materials provided that Chatillon has been notified in writing by buyer of the defect prior to termination of the warranty period. The goods are shipped to Chatillon with its written consent and with all shipping costs paid by the buyer, and the goods have been used under normal operating conditions. This remedy shall be buyer's sole and exclusive remedy in the event of Chatillon's breach of this warranty. This express warranty is in lieu of all other warranties express or implies, including the implied warranties of merchantability and fitness for a intended purpose, with the exception of the implied warranty of the title. In no event shall Chatillon be liable for any incidental or consequential damages resulting from its breach of contract or warranty.

Chatillon™
MEDICAL DYNAMOMETERS

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Appendix B-1

1997 CATALOG

Chatillon™

Made to Measure since 1835 SM

MEDICAL DYNAMOMETERS

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CHATILLON DYNAMOMETERS

Now there is a more cost effective alternative to those expensive computer controlled systems.

The Chatillon Dynamometers are designed to serve the needs of physical medicine, occupational medicine & sports medicine. Plus patient assessment in family practice, neurology and orthopedic surgery.

These completely portable instruments can easily be used in clinics, offices or hospitals to test arm, leg, and hand and back strength or in the field to perform a wide variety of job task analysis and ADA compliance evaluations.

The following is an excerpt from an article by Richard C. Bohannon in Muscle Strength Testing, Churchill Livingstone, New York, 1990.

Hand-held dynamometers like other force-asuring instruments, provide the clinician with an objective indication of muscle group strength. This objectivity is what distinguishes instrumented strength tests from manual muscle testing, which has been shown by Beasley to be insensitive to 20 to 25 percent changes in strength and to overestimate the normalcy of muscle strength.

One of the chief advantages of hand-held dynamometers is their portability. This characteristic allows considerable latitude in their clinical application. Unlike fixed dynamometers, they can be applied rapidly to different muscle groups independent of a large testing apparatus.Thus they are useful in environments such as home health where the use of other instruments may be impossible. The practicality of hand-held dynamometry is demonstrated by the patients of diverse diagnoses to whom hand-held dynamometry has been applied. These diagnoses/problems, to name a few, include poliomyelitis, stroke, muscle disease, motor neuron disease, Guillain-Barré ıdrome and other polyneurophies, joint-replacements, and alcoholism, moreover, healthy persons have been tested with the devices.

Reprinted with permission.

PHYSICAL MEDICINE

Accurately measure and document musculoskeletal strength. Evaluate individual muscle groups in flexion/extension, internal/external rotation, plantar flexion, dorsi flexion and abduction/adduction. Measure patient's progress.

OCCUPATIONAL MEDICINE

Conduct job task analysis, ergonomic analysis and functional capacity evaluations. Measure the actual push, pull or lift forces to determine exactly what a particular job task requires. Then quantitatively evaluate an employee's or prospective employee's ability to perform those tasks. Help ensure that an employee is really ready to return to work after an injury.

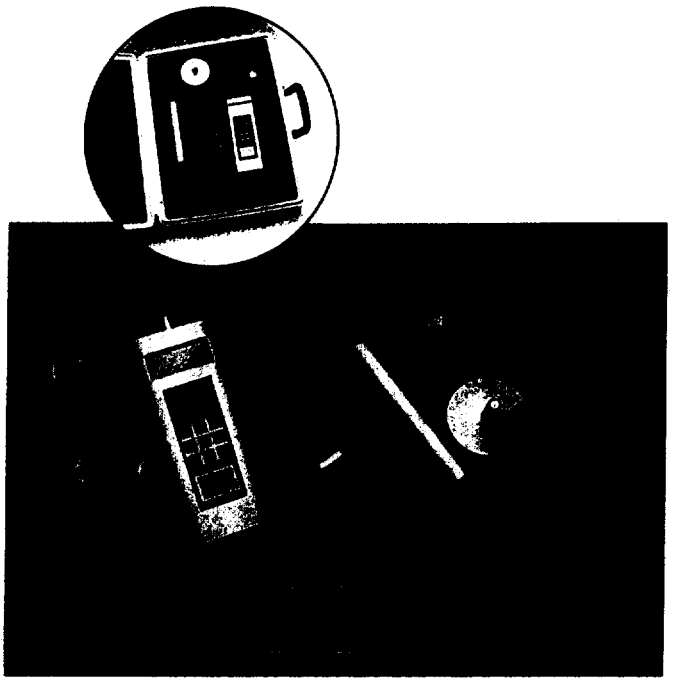
SPORTS MEDICINE

Objectively quantify an athlete's musculoskeletal force output. Evaluate and document the effectiveness of a prescribed training program. Serially track patient progress.

	CSD500	CSD400	CSD300	CSD200	CSD100
Capacity (lb)	500	100	500	500	250
Average Force	*	*	*		
C_V	*		*		
Left vs Right Comparison	*				
Analog Output	*	*	*	*	

FOR TASK ANALYSIS AND

The Chatillon CSD Dynamometers are precision force measuring devices that can be used in a wide variety of applications or settings including both job task and ergonomic analysis and manual muscle strength testing. Take these light and portable instruments into the field to accurately measure what the task requires.



MODEL CSD500C

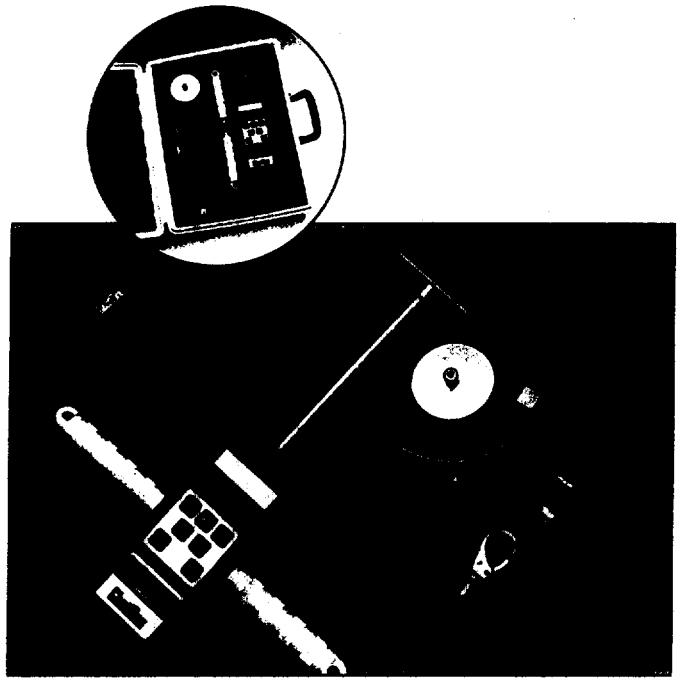
CSD500C - a 500 lb, electronic instrument with a remote load sensing element that is connected to the display by a coiled cable. It is a dual function unit that operates in either of two modes:

1. **Static Strength Testing Mode**, or
2. **Muscle Testing Mode.**

In the **Static Strength Mode**, the instrument stores data from 5 tests. The gauge will store in memory the Peak Force, the 3-second Averaged Mean Force, the trial to trial Force Variation (% Diff) and the Coefficient of Variation (C_V).

In the **Muscle Testing Mode**, the instrument compares the strength of a normal muscle to the strength of an impaired muscle. The normal muscle is tested until the Peak or breakaway force is reached or attained. This test is repeated two or three times to establish consistency of effort. The involved muscle is then tested in the same manner. The individual peak forces can then be displayed as well as the trial to trial Force Variation (% Diff) plus bilateral strength deficits.

The instrument is supplied with a complete set of attach facilitate both Job Task Analysis and Manual Muscle Strength Testing.



MODEL CSD300C

CSD300-C - a 500 lb, self-contained electronic instrument that measures the instantaneous forces over a fixed time period of 5 seconds. The peak force, measured during the 5 seconds, is stored in memory. The average force over the last 3 of the 5 seconds is computed and also stored in memory. The coefficient of variation (C_V) is computed after the second and each succeeding test and is also stored in memory. At the end of each test, the instrument displays the average push/pull force that occurred during the test period. The operator can then recall the peak push/pull force from memory using the keypad. The results of up to 5 tests can be stored in memory before the data must be recorded or sent out through a bidirectional computer port. The instrument is supplied with a complete set of attachments to facilitate both Job Task Analysis and Manual Muscle Strength Testing.

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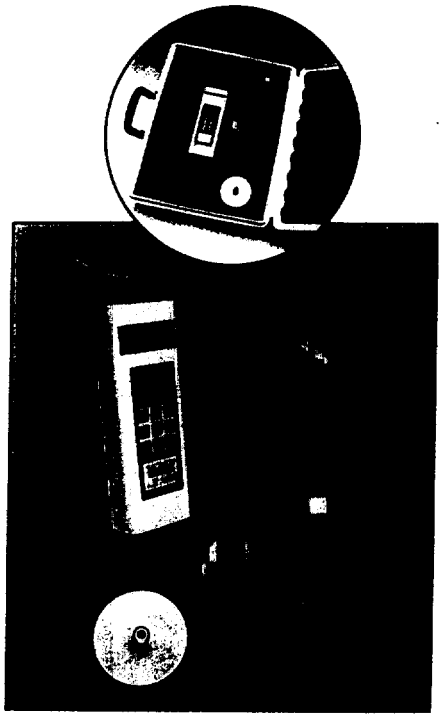
ND MUSCLE STRENGTH TESTING

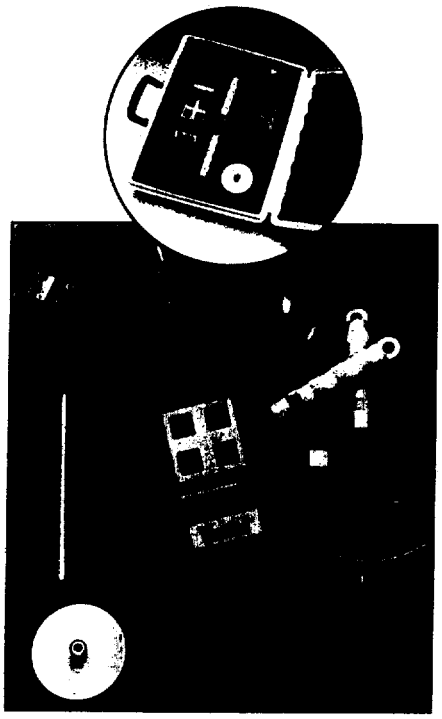
Then return to the clinic and measure the person's ability to perform the task using the same instrument.

The electronic instruments have rechargeable batteries to provide a full day of operation with an overnight charge.



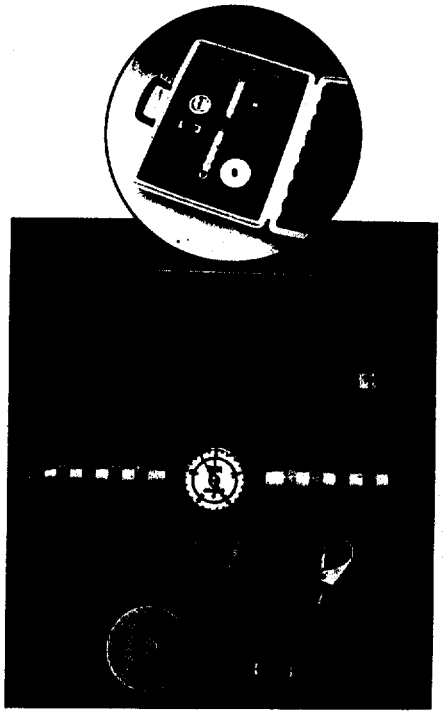
MODEL CSD400C

CSD400C - a 100 lb. self-contained electronic instrument that measures the instantaneous forces over a time period that is adjustable between 3 and 11 seconds. There is a two second delay at the beginning of the test to allow the person being tested to build to the required force slowly. At the end of the test, the instrument displays the Averaged Mean Push/Pull Force that occurred during the test period (after the delay). The operator can then recall the Peak Push/Pull Force that occurred from memory using the keypad. The results of five tests can be stored in memory before the data must be recorded or sent out through a bidirectional computer port. The instrument is supplied with a complete set of attachments to facilitate both Job Task Analysis and Manual Muscle Strength Testing.



MODEL CSD200C

CSD200C - a 500 lb, self-contained electronic instrument that measures instantaneous push or pull forces. The maximum value of force produced by a person during a single test is stored in memory. The results of each test must be recorded or sent out through a bidirectional computer port. The instrument is supplied with a complete set of attachments to facilitate both Job Task Analysis and Manual Muscle Strength Testing.



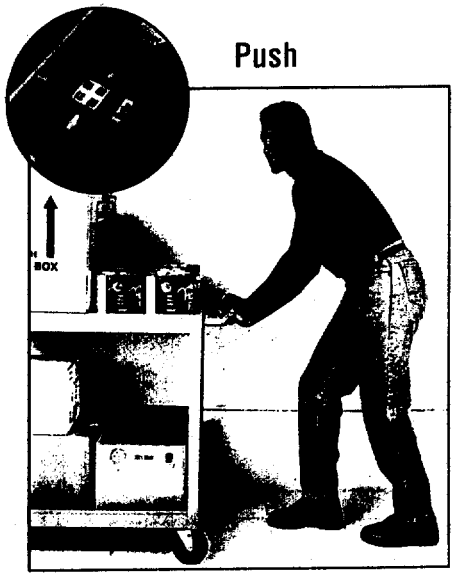
MODEL CSD100C

CSD100C - a 250 lb, mechanical instrument that measures the instantaneous push or pull force applied by a person and retains the maximum value of the force during a single test. A calibrated dial with a black reading pointer provides the instantaneous value and a red maximum reading pointer (MRP) stays at the high reading produced during a single test. The result of each test must be recorded before the MRP is reset for the next test. The instrument is supplied with a complete set of attachments to facilitate both Job Task Analysis and Manual Muscle Strength Testing.

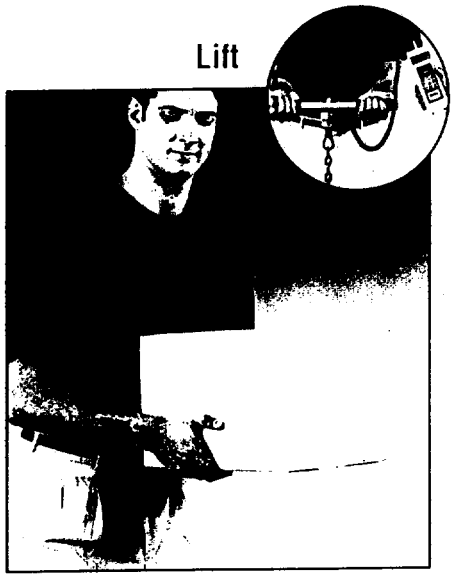
ELIMINATE ALL THE GUESSWORK

IN JOB TASK ANALYSIS

Push



Lift

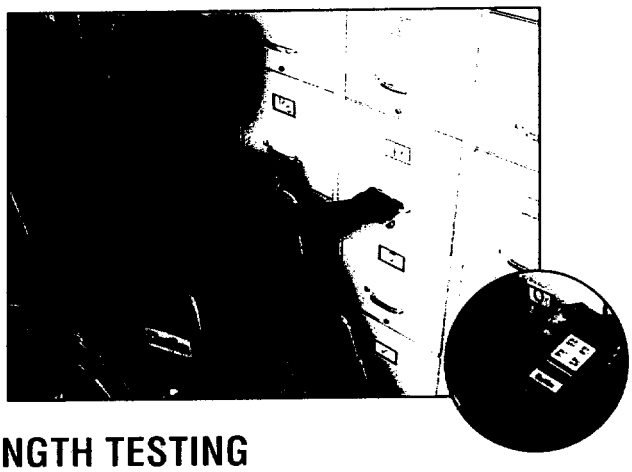


Pull

IN ADA COMPLIANCE

Push

Pull



IN MUSCLE STRENGTH TESTING

Flexion

Extension

Rotation

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LAFAYETTE INSTRUMENT

EVALUATION ASSESSMENT TOOLS

For Professionals in Private Industry
and
Medical Service Providers

- Human Resource/Recruiting Specialists
- Safety Professionals
- Industrial Hygienists
- Testing Specialists

Medical
- Occupational Therapists
- Physical Therapists
- Rehab Service Providers
- Chiropractors
- Orthopaedic Surgeons
- Occupational Health Professionals
- Psychologists

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Reference Guide
Volume 47

APPENDIX B-2 1997 CATALOG

TABLE OF CONTENTS

Lafayette Instrument®

3700 Sagamore Parkway North
P.O. Box 5729
Lafayette, Indiana 47903

317.423.1505
1.800.428.7545
Fax 317.423.4111
Lic@licmef.com
Rehab@licmef.com

GREETINGS!

Thank you for exploring our catalog. Some wonderful changes have occurred since our last issue and we wanted to share some of them with you.

Chris Fausett, Terry Echard and I purchased Lafayette Instrument Company from Bissell Healthcare late in 1995. We are all three members of the Management Team and are involved in long range as well as day-to-day issues. As I am in my early forties, I am the elder statesman of the group, so you can tell we will be here to serve you for a very, very long time.

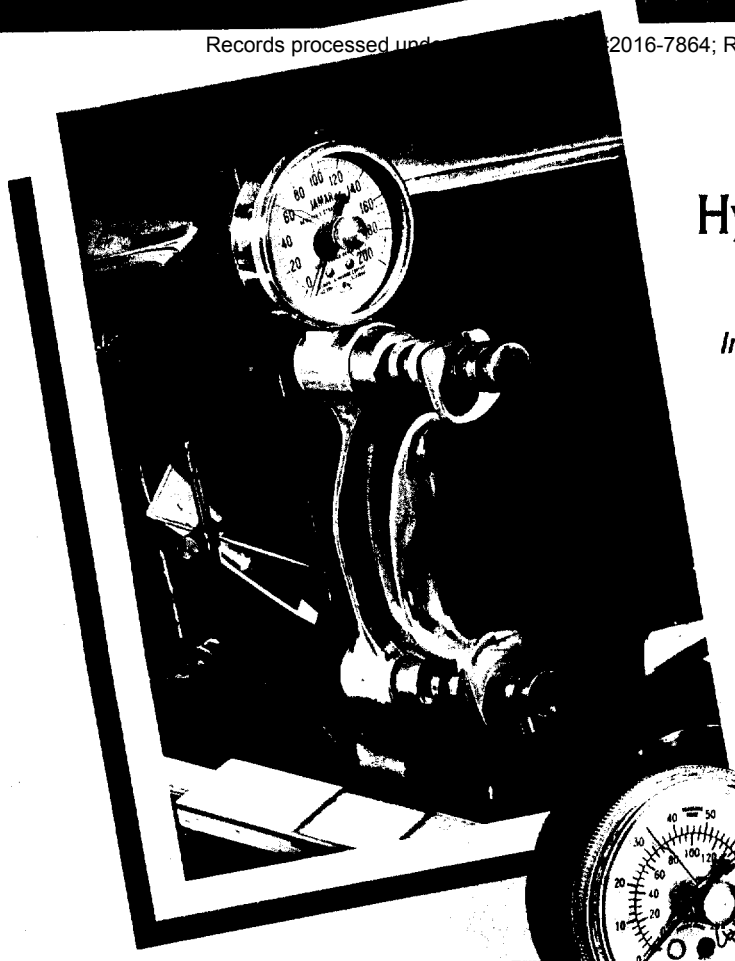
We have refined our scheduling and forecasting process, and are pleased to announce significantly reduced lead-times and tremendous improvements in our Customer Satisfaction. Our transition back to an entrepreneurial company, much like Max Wastl founded in 1947, has been very smooth and exciting. Our employee morale is at an all time high and we all look forward to the opportunity to serve you with your product needs.

We love to hear from our Customers about anything you want to talk about, good news or bad. We are very interested to learn from you any ideas you may have for new products or services you would like to see us offer. Feel free to give us a call and let us hear your ideas. It is a toll free call for you and a wonderful opportunity for us to learn more about our Customers and our marketplace.

Thank you for your patronage and consideration of Lafayette Instrument products. Please, give us a call...we would love to hear from you.

Roger McClellan
President

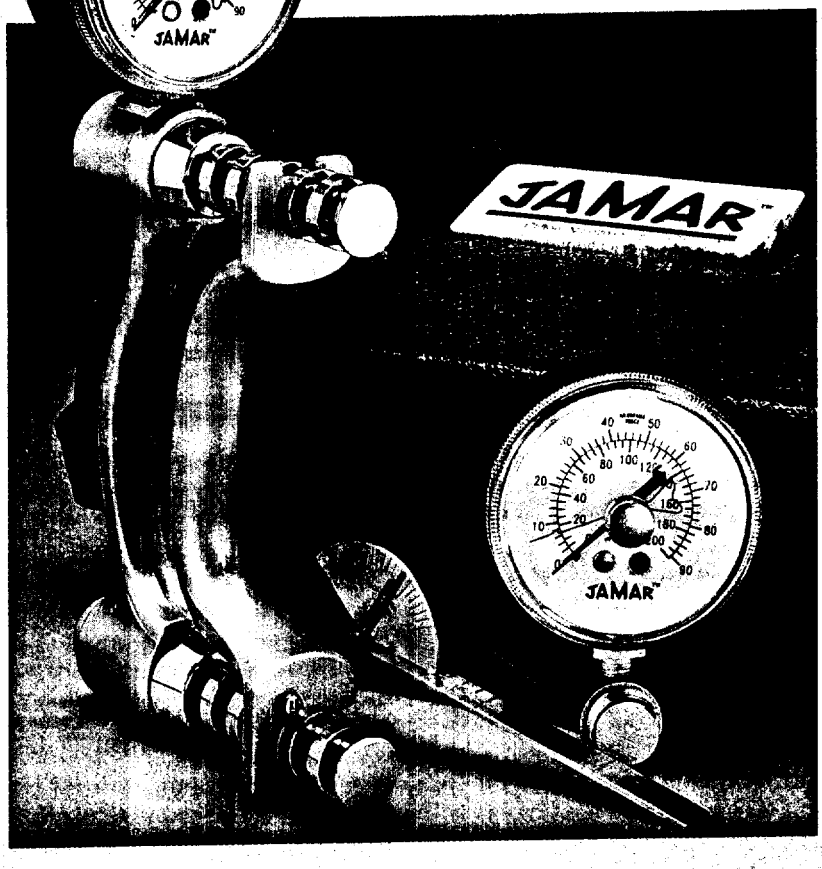
Serial Number 0396EC



In 1953, Dr. Morris Asimow Introduced the JAMAR™ Hydraulic Hand Dynamometer.

Dr. Asimow was Professor Emeritus of Engineering at UCLA. He was the author of *Introduction to Design* and was the recipient of the Master Designer award by *The Journal of Product Engineering.* His dedication to excellence can be witnessed in the classic design and unchallenged accuracy of the Hydraulic Hand Dynamometer.

In 1989, JAMAR™ Hand Dynamometers Set the New Standard for Quality in Grip-Force Evaluation.



Look closely at the new JAMAR™ Hydraulic Hand Dynamometer. Its classic design is familiar, but hidden from view is an updated hydraulic system that virtually eliminates leakage. A rubber, shock-absorbing cap protects the stainless steel gauge and a wrist strap helps prevent accidental drops.

Precision accuracy and improved durability represent the new generation of Hand Dynamometers from JAMAR™.

For information on the complete JAMAR™ diagnostic product line, including the new JAMAR™ Deluxe, call TOLL-FREE: 1-800-527-7530. In New Jersey, call: 201-777-8004.

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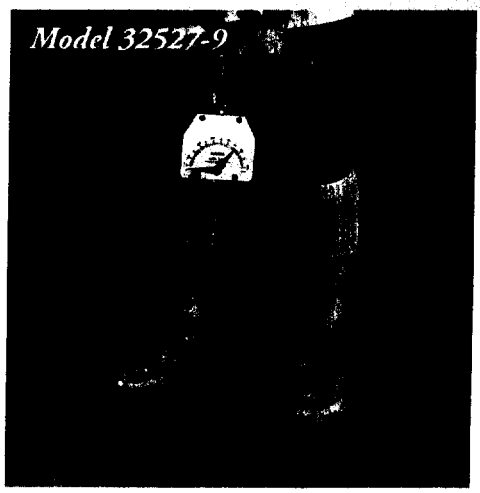
.olescent Back and Leg Dynamometer Package
Model 32527-3

Pediatric and adolescent subjects that have less strength than a full grown adult need an instrument that is easier to pull with greater resolution in the lower ranges. To solve this problem, we have devised a 300 pound dynamometer package. This package includes a 300 pound pull dynamometer, a 4 foot chain, a solid aluminum lifting bar with comfortable hand grips and a lifting platform. The solid birch, lifting platform, measuring 24 x 24 inches, is small enough for easy transportation. The pull dynamometer has several heavy-duty springs for long-lasting accuracy and a range of 25 to 300 pounds in 5 pound increments. All items in this package may be purchased separately.
Refer to Software Application on Page 9

Adult Back and Leg Dynamometer Package
Model 32527

Included in this package is a 600 pound pull dynamometer for testing subjects with normal strength and the same heavy-duty platform bar and chain found in our Adolescent package. The 600 pound pull amometer has a range of 50 to 600 pounds in 5 pound increments. ıtems in this package may be purchased separately.
Refer to Software Application on Page 9



Large Adult Back and Leg Dynamometer Package
Model 32527-9

This package is the same as our 300 pound package except that a 900 pound pull dynamometer is included with a range of 75 to 900 lbs.
Refer to Software Application on Page 9

Adult Cable Tensiometer Set
Model 32515

Therapists, trainers and exercise physiologists use this instrument to accurately evaluate isometric strength of the trunk, arms and legs. Included in this set is our 600 pound pull dynamometer, connecting cables and one each of a foot stirrup, shoulder harness, wrist cuff, thigh cuff and ankle cuff. Unit must be fixed with one cable attached to an immovable object like a wall. The dynamometer has a range of 50 to 600 pounds. All components are available separately.

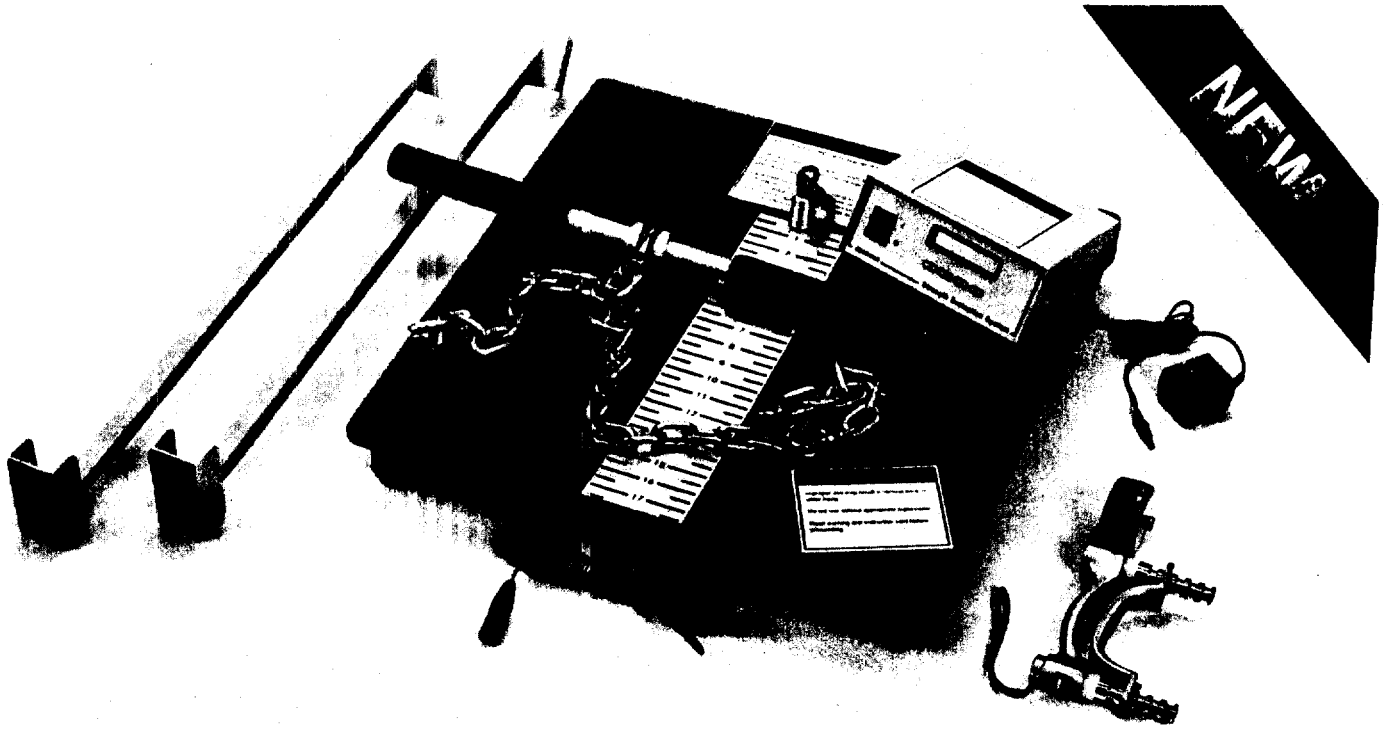
Pediatric Cable Tensionometer
Model 32516

This set includes all the straps and cable of our adult set but we substitute a 300 pound dynamometer, range 25 to 300 pounds.

acement Tensionometer Parts

Model 258-J00120	**Cable Set**	**Model 258-J00125**	**Foot Stirrup**
Model 258-J00130	**Shoulder Harness**	**Model 258-J00135**	**Wrist Cuff**
Model 258-J00140	**Ankle Cuff**	**Model 258-J00145**	**Thigh Cuff**

Jackson Evaluation System
Model 32628



Model 32628

The Jackson Strength Evaluation System includes:

32628CTL	Jackson Control and Load Cell
J00105	Jamar Hand Dynamometer
32628PBC	Lifting Platform, Bar & Chain

Model 32628 Dual
Optional System Includes:

32628CTL	Jackson Dual Control
32628PBC	Lifting Platform, Bar & Chain
32528HD	Hand Dynamometer
32528LC	Load Cell for Hand Dynamometer

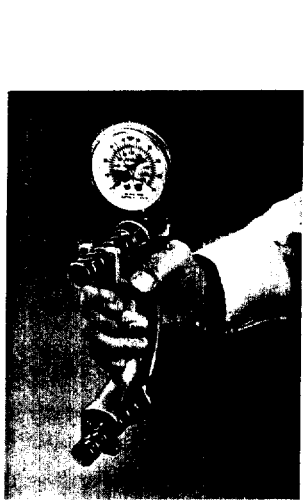
The Jackson Strength Evaluation system was developed by Dr. Andrew Jackson at the University of Houston. The Jackson system is widely used by rehabilitation professionals to monitor progress in recovery from injury and by industrial testing specialists to assess the physical ability of applicants for physically demanding work tasks. The system features an electronic load cell for accurate and reliable measurements of isometric strength and a new programmable microprocessor control, offering user defined or standardized test protocols. The system also includes a JAMAR hand dynamometer to measure grip strength and a heavy duty lifting platform, bar and chain. The Jackson system is designed to meet the needs of Jackson lift, torso and pull strength test protocols and the lift tasks of the National Institute of Occupational Safety and Health (NIOSH). The system comes complete with detailed instructions for most strength test protocols. Components of the system can be purchased individually. Additional features include:

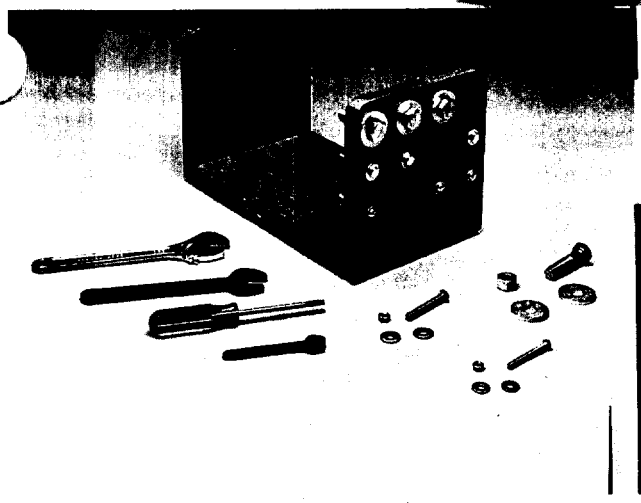
- Portable - for easy transportation to field sites
- Compact - will fit in the trunk of most automobiles
- Light Weight - Easy to carry and set up
- Microprocessor control - provides self calibration check, zeroing and stable (two years) calibration
- Validated - standardized for most pre-employment and pre-placement testing protocols

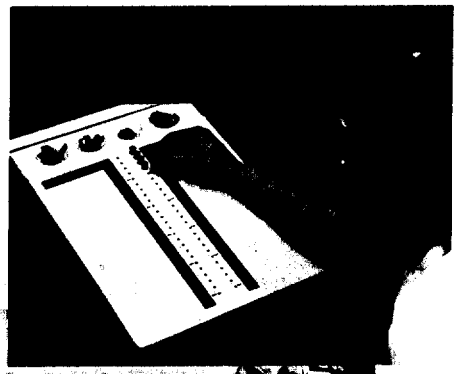
Available 220V/50Hz

Lafayette Instrument

is pleased to introduce six new standardized test batteries.







- Physical Work Capacity Pre-employment Evaluation System
- Functional Capacity Evaluation
- Mobile Vocational Evaluation Testing System
- Physical Work Capacity Fitness Evaluation System
- Occupational Skills Assessment
- Fit Kit

- Portable
- Economical
- Standardized
- Validated
- Documented
- Specific

For use by rehab service providers or by human resource testing professionals each test battery contains equipment and test protocols that may be used individually or in combination to assess recovery from injury, ability to return to specific job tasks, physical work capacity, general fitness and occupational skills. Several test batteries feature software to provide unambiguous scoring, analysis and print out of test results.

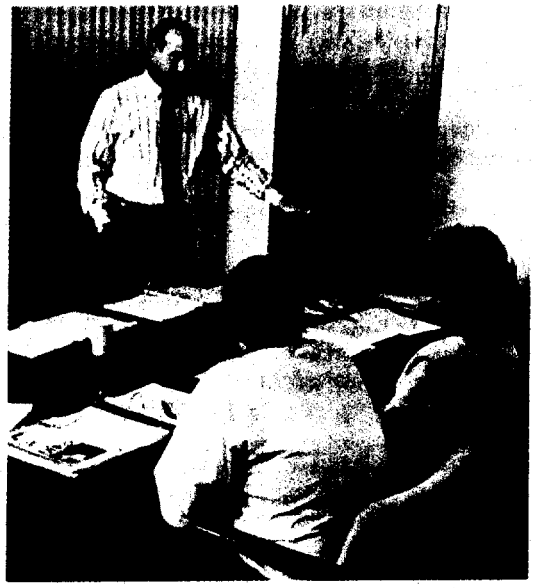
These batteries may be used in the workplace or in any rehab facility. The detailed descriptions on the following pages will help you determine which test battery best suits your testing needs.

Call for FREE Demo Disk

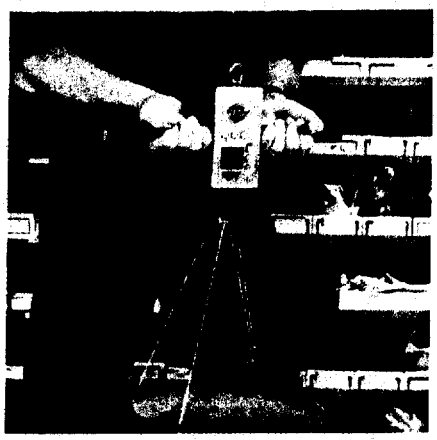
THE NEW NAME IN FUNCTIONAL CAPACITY TESTING GIVES YOU A LOT MORE FLEXIBILITY FOR A LOT LESS MONEY

Work and Job Simulation
The JobSim™ System handles all your work simulation needs from basic lifting to manual dexterity.

Training and Education
The Education Group at JTech Medical Industries offers a growing variety of training and continuing education courses - from in-depth seminars to on-site system certification - to meet your needs.

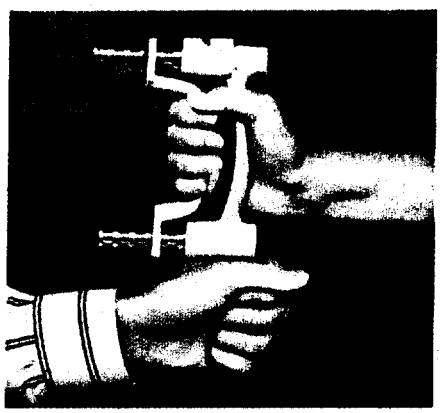


Functional Capacity Software
Windows-based Tracker FCE™ software gives you the flexibility to test and report using your own clinical style and evaluation techniques.



Lifting and Job Analysis
OnSite™ (on left) is the gauge that measures task lifting in your office and job related forces and weights in the field.

Hand Testing
From basic grip strength validity evaluation to comprehensive computerized testing, JTech manufactures a broad variety of hand testing systems.



JTECH

1-800-985-8324, 1-435-657-2500

http//www.jtechmed.com

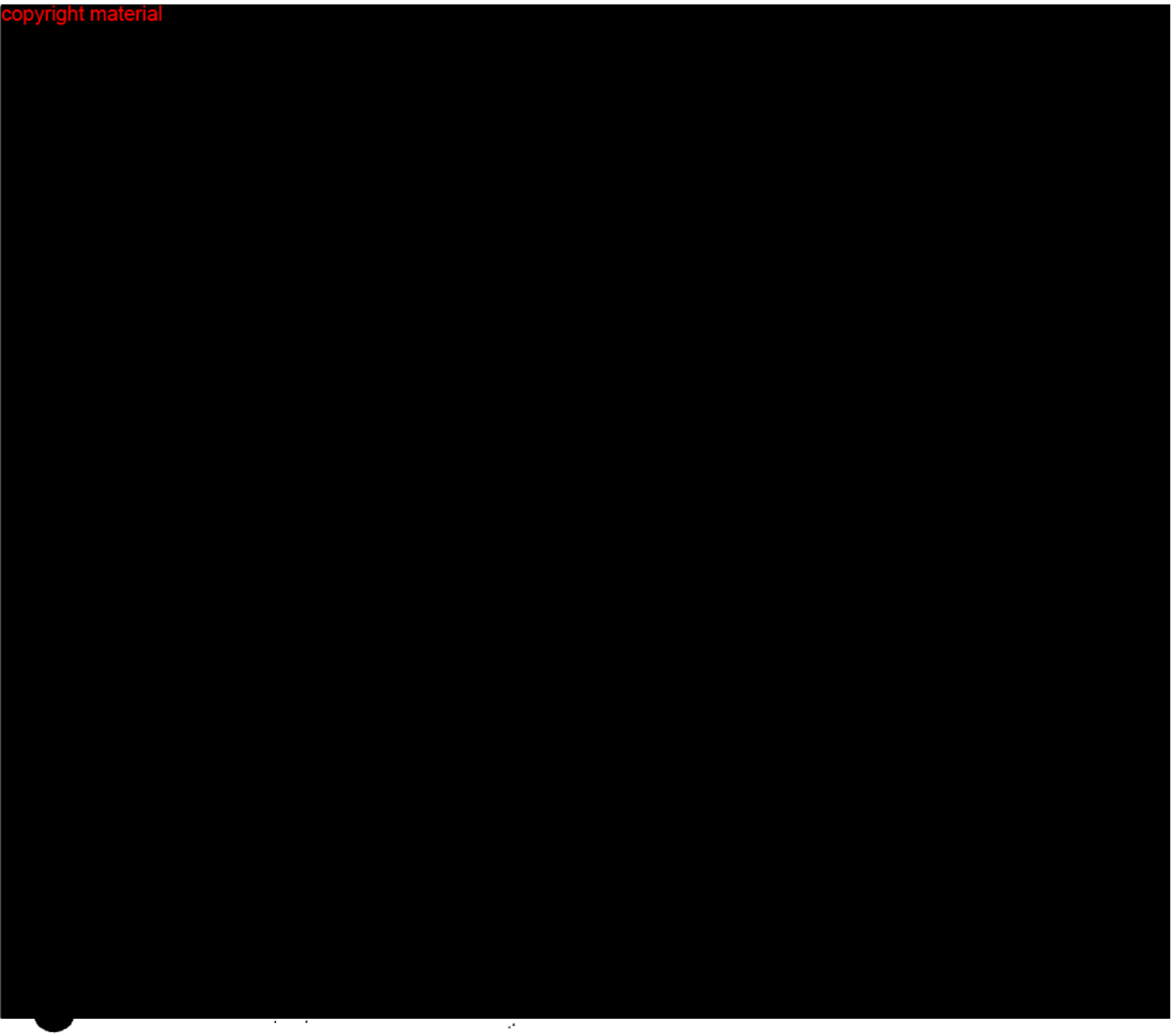
Circle 34 on Info Card

Appendix B3 1998 Advertisement 55

Ergonomics Guide for The Assessment of Human Static Strength

DON B. CHAFFIN, Ph.D.

Department of Industrial and Operations Engineering, The University of Michigan, Ann Arbor, Michigan



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PREEMPLOYMENT STRENGTH TESTING

In Selecting Workers For Materials Handling Jobs

Don B. Chaffin
Gary D. Herrin
W. Monroe Keyserling
James A. Foulke

The University of Michigan
Ann Arbor, Michigan

CDC-99-74-62

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Center for Disease Control
National Institute for Occupational Safety and Health
Physiology and Ergonomics Branch
Cincinnati, Ohio 45226

May 1977

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DISCLAIMER

The opinions, findings, and conclusions expressed herein are not necessarily those of the National Institute for Occupational Safety and Health, nor does mention of company names or products constitute endorsement by the National Institute for Occupational Safety and Health.

DHEW (NIOSH) Publication No. 77-163

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ABSTRACT

This research project was initiated to extend earlier studies which disclosed that weaker workers incurred a larger proportion of musculoskeletal problems when placed on jobs requiring significant physical effort than their stronger counterparts. The project entailed the evaluation of over 900 jobs in six plants to establish the relative strength requirements of each. For workers placed on these jobs, a medical history, physical examination, and physical activity history were documented. Also, isometric strength tests obtained in several different postures were obtained. During the period when workers were on one of the study jobs, all medical problems they incurred were carefully documented. Supervisors of these employees were also queried as to the worker's apparent ability or lack thereof to perform the physical aspects of the job. The data were collected over a one and one-half year period.

Several major findings resulted from this study. These are:

* The activity of lifting heavy loads, especially when done frequently, is associated with increased numbers and severity of musculoskeletal incidents.
* Weaker workers when performing high strength requiring activities, have an increased incidence and severity of musculoskeletal and contact type injuries.
* Strength varies greatly in the working population and is not well predicted based on gender, age, body weight, or stature.
* Strength which relates to personal risk of later injury can be equally assessed by testing a worker in postures which are standardized or which reflect the maximum load related postures required on the job.

New in-depth biomechanical and metabolic job evaluation methodologies are also employed on selected jobs which demonstrate how re-engineering could be accomplished to reduce the potential for different types of musculoskeletal injuries.

A recommendation is proposed that an action level be developed to control the hazards of excessive physical exertions for weaker workers. Such an action level would reflect a concern for the adverse effects of load magnitude, load handling frequency, and load size and/or location on a job. If these conditions exceed the prescribed action level, then a medical examination with strength assessment would be required for all workers going onto such jobs. Also, such an action level when exceeded would require a biomechanical evaluation of the job to determine the type of engineering redesign which would be most effective in reducing the hazard levels.

Other recommendations regarding type of strength testing and their potential contributions to worker health and safety are given.

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CHAPTER IV

ASSESSMENT OF EMPLOYEE STRENGTH

(b)(4) Testing

[redacted]

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Preemployment Strength Testing

An Updated Position

Don B. Chaffin, Ph.D.; Gary D. Herrin, Ph.D.; and W. Monroe Keyserling, M.S.

This investigation was conducted to evaluate the practicality and potential effectiveness of preemployment strength testing in reducing the incidence and severity of musculoskeletal and back problems in materials handling jobs. Prior to assignment to new jobs, 551 employees in six plants were given a series of strength tests and then monitored for approximately 18 months. During this time, all medical incidents were documented. An analysis of these incidents revealed that a worker's likelihood of sustaining a back injury or musculoskeletal illness increases when job lifting requirements approach or exceed the strength capability demonstrated by the individual on an isometric simulation of the job. Because strength was found to be weakly correlated with other individual attributes (e.g., gender, age, weight, and stature), the authors conclude that industry should implement specific employee selection and placement programs using a strength performance criterion.

Earlier papers by these authors and others have supported the concept that the incidence and severity of musculoskeletal illness or injury can be reduced on jobs requiring physical exertions.[1,2,3] It has been proposed that such a reduction can be achieved by selectively employing workers who can demonstrate strengths in standardized tests which are as great or greater than that required in the normal performance of their jobs.[1,4] In the course of this type of research, many basic and practical questions have been raised. For instance: What type of strength tests are effective? How many tests must be performed? What are the risks to the p[illegible]ctive employee during the tests? How much strength is [illegible]d to be "protective"?

From the University of Michigan, College of Engineering, 2260 G. G. Brown Lab., Ann Arbor, MI 48109.

Because of these and other questions, and the obvious fact that if strength testing were to be performed for preemployment purposes, it would necessarily deny employment to proportionally more women and older employees, another longitudinal study was initiated under a NIOSH contract in 1974.

The specific objectives of this latest study were: (1) To develop and utilize a set of isometric lifting tests to predict the strength capacities that a heterogeneous group of workers can produce on their jobs; and, (2) To statistically estimate the degree and type of personal risk that exists when a person is required to perform an exertion on a job which exceeds his/her strength capacity as measured by standardized isometric strength tests administered at the initiation of the job assignment.

The first objective required the formulation of a rational strength testing program for employees assigned to jobs requiring a known amount of physical exertion, particularly exertions involving load lifting. The second objective required the systematic evaluation of employee strengths upon entering jobs having physical exertions, and then following each employee's medical status while assigned to such job.

Methods Developed for Subject Strength Testing

Several criteria were considered important in developing the type of strength testing needed in the future. First, any such procedure must be safe. This criterion precluded having people attempt to lift specific objects (i.e., bar bells, tote boxes filled with lead shot, steel bars, etc.), since to do so would expose the person to the hazards of both dropping the object on a foot and the dynamic stresses imposed by the motion imparted to the object. Based on this thinking, an isometric test was proposed. In such a

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This study was performed to develop and evaluate a scheme for matching the strength of workers to the strength demands of their jobs. Biomechanical analyses were performed on production jobs in an aluminum reduction plant to identify and quantify strength demands. These data were used to design a set of nine strength tests which simulated job activities with the greatest strength requirements. A cross section of plant employees assigned to these jobs was strength tested and monitored for medical incidents for a period of over two years. Significant relationships were found among job strength requirements, worker strengths, and medical incidents. Workers with strength abilities (as determined by the tests) less than job strength requirements suffered a higher rate of medical incidents than workers whose strength abilities matched or exceeded job demands. It was concluded that strength testing can be used to identify workers who would be at increased risk of suffering medical incidents if placed on jobs which exceeded their strength abilities.

Establishing an industrial strength testing program

W. MONROE KEYSERLING, Ph.D.,[A] GARY D. HERRIN, Ph.D.,[B] DON B. CHAFFIN, Ph.D.,[B] THOMAS J. ARMSTRONG, Ph.D.,[C] and MERLE L. FOSS, Ph.D.[D]
[A]Harvard School of Public Health, Boston, MA 02115; [B]College of Engineering, the University of Michigan, Ann Arbor, MI 48109; [C]School of Public Health, The University of Michigan, Ann Arbor, MI 48109; [D]Department of Physical Education, The University of Michigan, Ann Arbor, MI 48109

Introduction

Manual materials handling is recognized as the leading cause of occupational illness and injuries in the United States and accounts for approximately twenty-five percent of all workers' compensation payments.[1,2] Most of these costs are due to the long periods of incapacitation and rehabilitation which result from injuries to the lower back. Studies conducted over the past two decades have shown an increased incidence and severity of low back pain in occupations which require the lifting and moving of heavy loads.[3-6] In addition to the low back problem, positive relationships have been found between the occurrence of common occupational injuries (bruises, abrasions, lacerations, sprains, etc.) and overexertion in manual handling activities.[7] All of these injuries may be compensable under recent legal interpretations of cumulative injury.[8]

It is apparent from the above discussion that manual materials handling activities present a serious problem to today's occupational health professional. Several solutions have been suggested to alleviate the problem, but they generally have been ineffective. In a recent survey of workers' compensation policy holders, it is reported that neither employee training programs in safe lifting techniques nor traditional medical screening programs (based on medical histories or low back X-rays) have resulted in any reduction in low back injuries.[9] This finding is consistent with other studies.[10-12] The survey concludes that the most effective method of controlling injuries is to design jobs to fit the worker and that such a policy could reduce overexertion injuries by as much as 67 percent.[9]

Job redesign is the *ideal* solution to the manual material handling problem. Required loads should be reduced to accomodate the strength of the working population and/or mechanical assistance should be provided for employees to reduce wear and tear on their musculo-skeletal systems. Unfortunately, the above suggestions often require extensive engineering redesign and may not be feasible to implement in existing plants. In these situations, an alternative *and interim* solution is to establish a program for selecting workers based on their ability to perform the strength requirements of their jobs.

This investigation was undertaken to develop and demonstrate a system for assessing workers' abilities to perform strenuous job elements. This system was based on isometric strength testing for the reasons outlined in the next section. The specific objectives of this study were:

1. To use isometric strength tests to measure worker strengths in simulations of strenuous job elements and
2. to determine the relationships among worker strength attributes, job requirements, and medical incidents.

Criteria for evaluating tests of physical ability

There are several different methods which have been used to evaluate a workers' ability to safely handle heavy loads in a future job. In selecting a method for this investigation, the following questions were addressed:[13]

Is the procedure safe to administer?
Does it give reliable, quantitative results?
Is it related to specific job requirements?
Is it practical?

The work reported in this paper was partially supported by the ALCOA Foundation, Pittsburgh, PA, and NIOSH Training Grant #5-T01-OH00161-06.

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510K Submission to the FDA

DIGIT–grip with Attachments (Ultimate Series)

APPENDIX C

NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, Minnesota 55441
Telephone: (612) 541–0411
Fax: (612) 541–0863
Toll Free: (800) 462–3751

N.K. BIOTECHNICAL CORPORATION

STATUS LIST - N.I.S.T. TRACEABLE STANDARDS 01/15/98

PRIMARY STANDARDS -	CAL. DUE DATE.
VOLTAGE AND RESISTANCE:	
HP3457A MULTIMETER S.N. 2538A01321	12/10/98
FORCE: LEBOW LOAD CELL MODEL 3132-1K SN9975.	09/10/99
DEAD WEIGHT SET A - NINE 1 KG. SLOTTED WEIGHTS (A1-A3,A5-A10), RICE LAKE WEIGHING SYSTEMS.	7/17/99
DEAD WEIGHT SET C - 11 MISC. WEIGHTS	7/17/99
DEAD WEIGHT SET B - 10,20,20,50 GM.	7/17/99
DEAD WEIGHT SET H - 32 MISC. WEIGHTS.	7/17/99
DEAD WEIGHT SET E - 5 EACH 1,5,10,20 G	7/17/99
LENGTH: FOWLER DIAL CALIPER 0-6" SN Q853715	01/12/00
ANGLE : ANGLE BLOCKS S.N. 95010 AND S.N. 95011	~~03/30/98~~ 4/27/2001

TRANSFER STANDARDS -	
VOLTAGE SOURCE:	
GEN. RESISTANCE DIALABLE VOLTAGE REFERENCE MODEL DAV46G S.N. 964	12/31/98
RESISTANCE SOURCE:	
GEN. RESISTANCE DECADE BOX 53-3X S.N. 290	12/31/98
GEN. RADIO DECADE BOX 1434-P S.N. 10691	12/31/98
VOLTAGE MEASUREMENTS: HP3497 DACU S.N. 2222A09780	12/31/98
VOLTAGE AND RESISTANCE MEASUREMENTS:	
KEITHLEY 199 SYSTEM DMM SN429036	12/31/98
HP3468B BENCHMETER S.N. 959281	12/31/98
HP3468A BENCHMETER S.N. 2137A15330	12/31/98
HP3468A BENCHMETER S.N. 2137A06654	12/31/98
FORCE: INTERFACE LOAD CELL MODEL SM-500 SN B20216	01/05/99
LEBOW LOAD CELL MODEL 3132-500 SN11115	01/05/99
LEBOW LOAD CELL MODEL 3397-100 SN8556	12/31/98
N.K. HAS CALIBRATOR LC001 S.N. 005	12/31/98
RICE LAKE LOAD CELL MODEL 1010 S.N. 798334	01/05/99

NK BIOTECHNICAL CORPORATION
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Phone (612) 541-0411 FAX (612) 541-0863
Toll Free (800) 462-3751

CERTIFICATE OF CALIBRATION

Sample Form

This is to certify that the device listed below has been calibrated using either instruments and deadweights, or instruments and reference load cells, which are traceable to the National Institute of Standards and Technology.

Calibration records for this device and for calibration standards used by NK Biotechnical Corporation are on file and available for inspection.

DEVICE	MODEL	SERIAL NUMBER	CALIBRATION DUE DATE
DIGIT-grip DEVICE with LCD DISPLAY	DGR002	904088 906017	SEE BELOW **

		POST 1	POST 2
INPUT RESISTANCE	(OHMS) =	1234.6	1234.8
OUTPUT RESISTANCE	(OHMS) =	1003.5	1003.3
RESISTANCE TO GROUND	(MEGAOHMS) =	>20,000	>20,000
DEVICE OUTPUT	(mV Equivalent @ 100 KG) =	4.180	
CALIBRATION CONSTANT	=	11B7	
LCD INTERNAL SOFTWARE VERSION	=	1.16	
PRECISION CHECK (DISPLAYED VALUES)	=	100 KG (220 LB)	
ACCURACY	=	+/- 1 %	

** Physical recalibration of this Device is required only when the Self-Diagnostic Software indicates a Device Failure.

Calibrated by: William Moilanen
William Moilanen, Metrologist

Date: 02-07-97

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Toll Free (800) 462-3751

CERTIFICATE OF CALIBRATION

NK ULTIMATE SYSTEM

This is to certify that the device listed below has been calibrated using either instruments and deadweights, or instruments and reference load cells, which are traceable to the National Institute of Standards and Technology.

Calibration records for this device and for calibration standards used by NK Biotechnical Corporation are on file and available for inspection.

DEVICE	MODEL	SERIAL NUMBER	CALIBRATION DUE DATE
LCD Display With Load Cell 500#	DGR002	906068 98004	SEE BELOW **

INPUT RESISTANCE	(OHMS)	=	432.3
OUTPUT RESISTANCE	(OHMS)	=	349.2
RESISTANCE TO GROUND	(MEGAOHMS)	=	>20,000
DEVICE OUTPUT	(mV Equivalent @ 100 KG)	=	2.165
CALIBRATION CONSTANT		=	2235
LCD INTERNAL SOFTWARE VERSION		=	1.175
PRECISION CHECK (DISPLAYED VALUES)		=	100 KG (220 LB)
ACCURACY		=	+/- 1 LB
BIPOLAR (Push-Pull Capability)		=	YES
MEASUREMENT RANGE		=	0-225 KG (0-500 LB)

** Physical recalibration of this Device is required only when the Self-Diagnostic Software indicates a Device failure.

Calibrated by: William Moilanen
William Moilanen, Metrologist

Date: 05-01-98

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

December 10, 1996

Karen M. Gotfredson, President
NK Biotechnical, Corp.
10850 Old County Rd 15
Minneapolis, Minnesota 55441

Dear Ms. Gotfredson:

The Food and Drug Administration conducted an inspection at your medical device facility on Old County Road 15 on October 25, 1996. The inspection covered your hand mobility monitoring devices.

The areas inspected appear to be in substantial compliance with the applicable requirements of the Federal Food, Drug and Cosmetic Act and implementing regulations.

Based on these findings, the Agency is prepared to endorse applicable pending pre-market submissions and Export Certificates for products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when considering the award of contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The Agency may separately inspect your firm's facilities to address GMPs in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits to ensure you are continuing to maintain conformance with GMPs.

For future information, please contact the following individual at this office:

Edwin S. Dee
Director
Compliance Branch
Minneapolis District
(612) 334-4100 ext. 154

Sincerely yours,

John Feldman
Director
Minneapolis District

TPN/ccl

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WARRANTY FOR
NK DIGIT-grip Device

For a period of two (2) years, NKB warrants the product to be free from defects as to all electro-mechanical parts (sensors).

For a period of one (1) year, NKB warrants the product to be free from defects as to all mechanical parts including removable handle, cables and connectors.

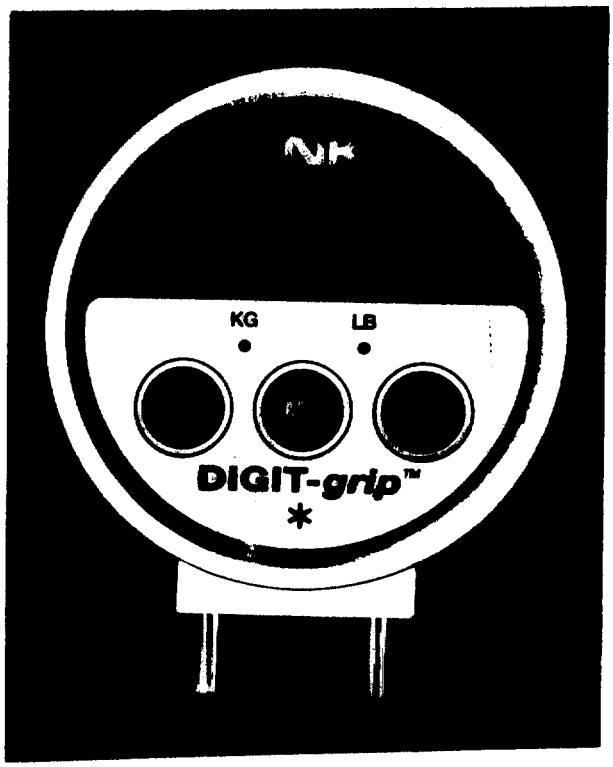
LCD Display

For a period of one (1) year, NKB warrants all components to be free from defects.

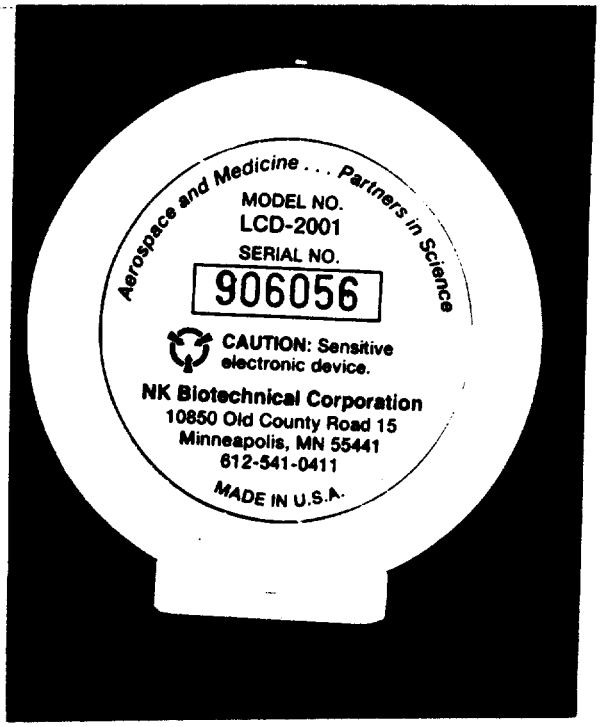
The above warranties shall not obligate NKB in any manner whatsoever with respect to, and shall not be applicable to, any defects which after inspection by NKB are not, to NKB's reasonable satisfaction, demonstrably the result of defective parts, materials or workmanship. NKB is not liable for consequential or contingent damages and its liability is strictly limited to the original purchase price of the product or its repair or replacement, at NKB's option. NKB should be immediately notified of any suspected warranty claims. All transportation and insurance charges for returned merchandise are to be prepaid by the customers. All warranties for repairs are off-site only. If device has been tampered with or bears any evidence of dissambly, all warranties are void.

The foregoing warranty is in lieu of all other warranties or guaranties, expressed or implied, and of all other obligations on the part of NKB, whether in contract or tort. This warranty shall be void if the NKB product has been in any way tampered with, altered or repaired by persons unauthorized by NKB; has been subjected to misuse, negligence or accident, or has been installed, adjusted or used otherwise than in accordance with the instructions furnished for the user of the subject product.

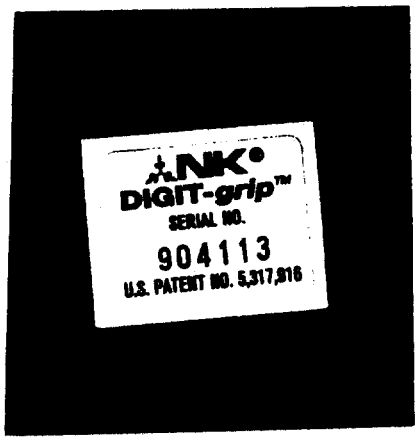
NK Biotechnical Corporation
10850 Old County Road 15, Minneapolis, MN 55441
Telephone (612) 541-0411; Toll Free (800) 462-3751; Fax (612) 541-0863



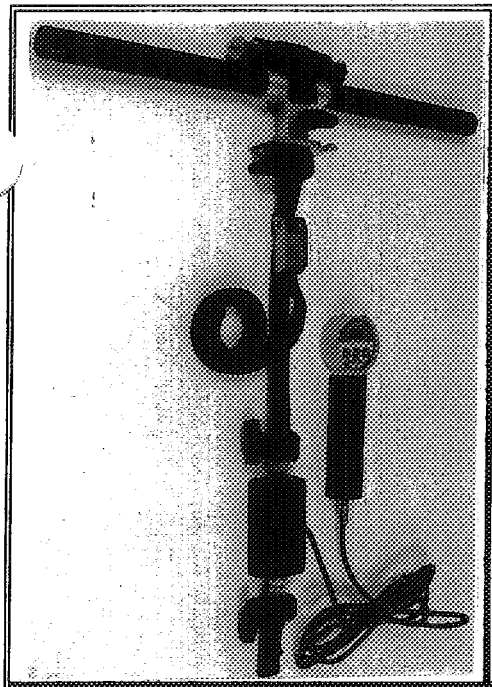
LCD Front Panel



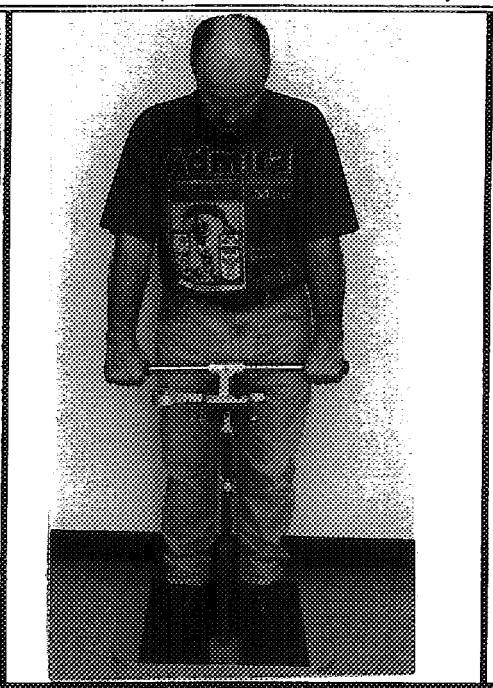
LCD Back Panel



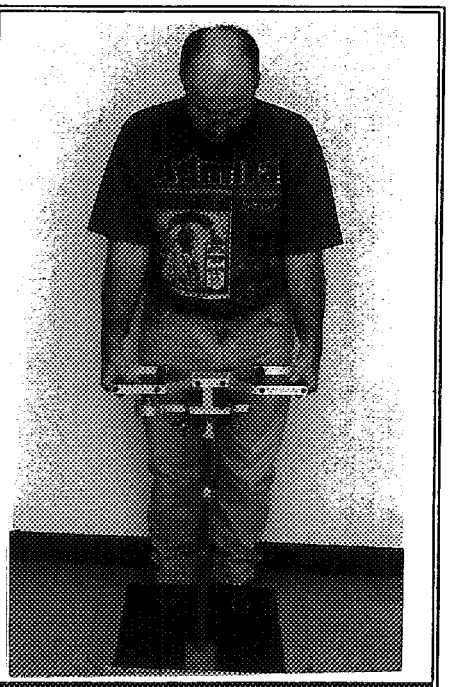
DIGIT-grip Body Bottom Panel



13 – T-Bar Assembly (500# Capacity)

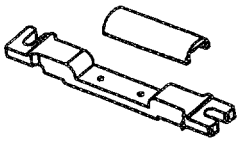


14 – T-BAR Assembly (220# Capacity)



15 – Totepan Assembly (220#

1 –
2 –



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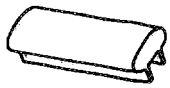

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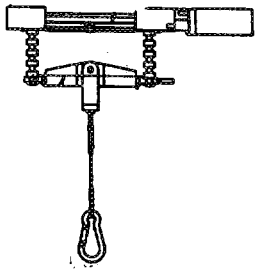
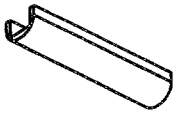


13 – See Above

14 – See Above

15 – See Above

3 –



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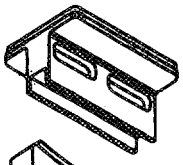

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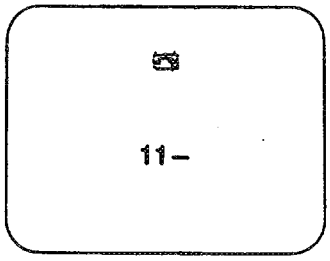

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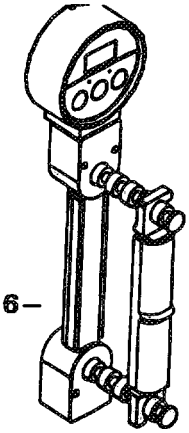

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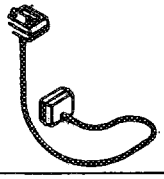

12 – Not Shown

SYSTEM COMPONENTS

ULTIMATE Force Measurement System

ULTIMATE SYSTEM COMPONENTS

1 – Child's Grip Handle (ULT001)
2 – Pinch Handle (ULT002)
3 – 10 Position Grip (ULT003)
4 – Wide Flat Push Handle (ULT004)
5 – Concave Push Handle (ULT005)
6 – Palmar Handle (ULT006)
7 – Half Grips (ULT007)
8 – LCD 180 Degree Adapter (ULT008)
9 – LCD Extension Cable (ULT009)
10 – Pull-Lift Cable Assembly (ULT010)
11 – Footplate (ULT011)
12 – Custom Carrying Case (ULT012)
13 – T-BAR Lift Assembly (ULT013)
14 – T-BAR Assembly with DIGIT-grip (ULT014)
15 – Totepan Assembly with DIGIT-grip (ULT015)
16 – DIGIT-grip with LCD Display (DGR002)

510K Submission to the FDA

DIGIT–grip with Attachments (Ultimate Series)

APPENDIX D

NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, Minnesota 55441
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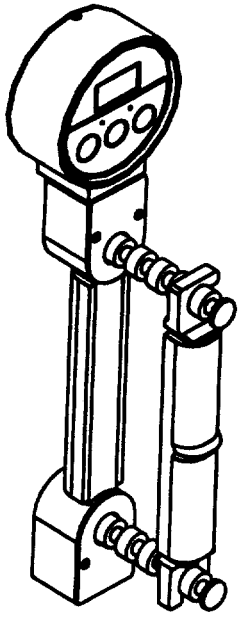
Fax: (612) 541–0863
Toll Free: (800) 462–3751

TM

DIGIT*grip* — LEVEL ONE

for Stand-Alone Operation



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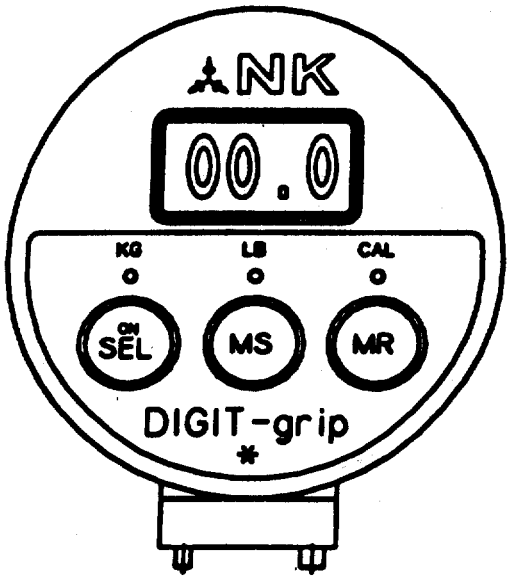
Introduction —

The DIGIT-grip, when operated as a stand-alone, non-computerized device, utilizing the battery powered LCD processor and internal software, includes two distinct modes of use:

1. the IMPULSE Mode, and
2. the SUSTAINED Mode.

In both of these Modes, all functions are performed using the three round Selection Buttons located on the face of the LCD Display.

The LCD Display Face is reproduced below with the three Selection Buttons described for easy reference.



DISPLAY 00.0

SELECTIONS BUTTONS:

SEL *Turn On – Select Patient*

MS *Memory (Data) Storage*

MR *Memory (Data) Recall*

RESET BUTTON *

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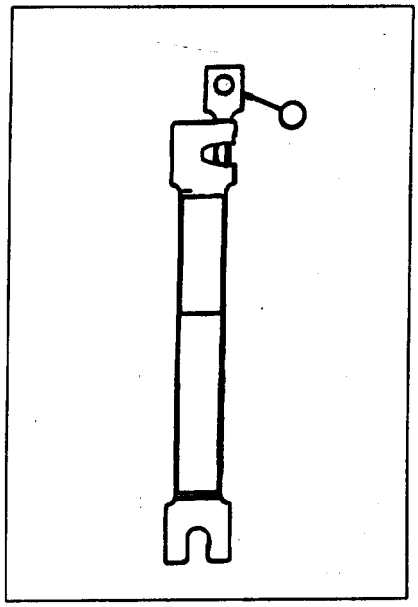
General Operation Instructions —

1. ALWAYS install the DIGIT–grip Handle so that the locking mechanism is at the TOP of the device. ALWAYS be certain that the handle CLICKS into place before applying any loads to the device. A Blue Safety Pin is installed on the DIGIT–grip. This Pin MUST be engaged in the handle during testing to assure that it remains securely locked in place.

   Failure to follow the above directions may result in the handle slipping during testing – which can cause serious damage to a device post.



2. The LCD'S internal software program automatically initiates a self–test routine each time the device is turned on. If the device passes the self–check, the calibration value will display momentarily, the Mode (Impulse or Sustained) indication will display next and finally the display will return to [0.0], indicating it is ready to com–mence testing. (If the Device is in the Sustained Mode, the Averaging Time [2] will also display following the calibration value.

3. If the internal automatic self–test routine fails calibration, the word CAL will flash on the display. The display will then go blank, and the device will not allow testing. Call the NKB Help Line (800–462–3751) as some type of failure has occurred. For example, the device will not pass the self–check if it has been dropped and the resultant impact has caused some internal damage or if one of the device posts has been bent and damaged by handle slippage during testing.

4. To preserve battery power, the LCD Display Module has an internal shut–off feature. If no Selection button has been pushed and no force in excess of one kilogram (two pounds) has been applied to the handle for 70 seconds, the display will go blank and the device will turn off. All unsaved data will be lost. Press the ON SEL button to turn the device back on.

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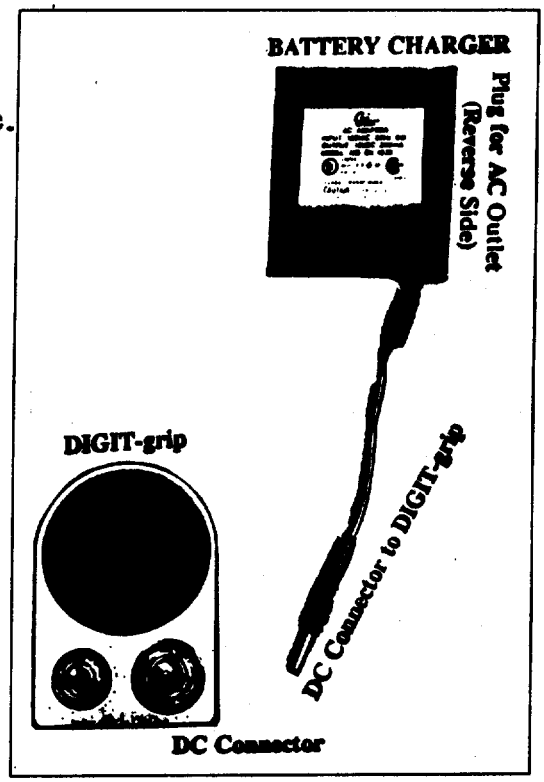
(Continued)

— General Operation Instructions

5. **Once data has been stored in memory, it will NOT be lost due to shutting itself off or battery failure.**



6. Pressing the Reset (*) Button at the bottom of the LCD Display will reset the device. If for any reason, the device locks up, pressing the Reset Button will allow testing to continue.

7. Test results can be displayed in kilograms or pounds. The green light below the Kg and Lb on the LCD Display face indicates the current setting. To toggle between kilograms and pounds, simultaneously press the [SEL] and [MS] Buttons.

8. The DIGIT–grip device is shipped with a Calibration Certificate showing the device's performance, traceable to NIST Standards and a product warranty certificate. Failure to follow the above instructions is considered misuse and may void all warranties of the Company.

9. The DIGIT–grip device is zeroed (reset) by pressing the * key. ALWAYS be certain that NO LOAD is being applied to the handle at the time the device is reset. If any load is being applied to the handle, the device will zero and instead of displaying [00], it will offset by the amount of force that was applied to the handle. For example, if a force of 5.0 lbs was indvertently applied at the time the device was reset, the LCD will display [–5.0] at the time the * key is released. Then for all tests run, the device would begin at –5.0 rather than zero, resulting in the test score always being 5.0 lbs low in the case of Push tests and 5.0 lbs high in the case of Pull/Lift Tests. To remedy this problem, rezero (reset) the device.

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(Continued)

General Operation Instructions (Battery)

1. **Battery Specifications for Standard 60 mA Battery: ****

Battery Fully Charged	**7.7 Volts**
Design Battery Capacity	**60 mA – Hour**
Battery Discharge Rate when LCD is ON	**6.7 mA**
Battery Life – LCD is ON continuously	**9.0 Hours**
Battery Life on Shelf	**100 Days (14 Weeks)**

2. The Low Battery Warning: **BAT** will display on the LCD when the battery voltage drops to the level where it must be recharged before further use. Once this occurs, the device will shut itself off. You may continue to use the device for testing, only if it is plugged into an AC outlet as its power source.

   When the voltage drops to this level, to fully recharge it will take a MINIMUM OF 12 HOURS.

   As stated in the above specifications, under constant use (load on the DIGIT–grip handle), the LCD battery will fully discharge in approximately 9.0 hours. This can occur under any of the following circumstances:

   a. On rare occasions, the LCD Display will "lock up." When this occurs the LCD will not automatically shut itself off and the battery will continue to drain. To remedy this, immediately press the Reset Button [*] to return the Display to normal operations.

   b. Inadvertently disconnecting the LCD Display from the DIGIT–grip body while the LCD is active will result in the LCD Display locking up and remaining in the ON position, causing the battery to discharge. Before removing the LCD Display from the device body, ALWAYS be certain the LCD Display has first automatically turned itself off.

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(Continued)

— General Operation Instructions (Battery)

PROTOCOLS FOR BATTERY CHARGING

1. The DIGIT-grip Battery Charging System is equipped with the following features for monitoring the charging process:

   → A White Adapter Unit with a Red LED Light that interfaces the cable with an AC Wall Outlet.
   → A Red LED Light installed in the body of the DIGIT-grip Device.

2. To charge the LCD Battery:

   → Securely connect the LCD Display to the DIGIT-grip Body.
   → Connect the DIGIT-grip Body to the Battery Charging Cable.
   → Connect the Battery Charging Cable to the White Adapter Unit.
   → Plug the White Adapter Unit into the AC Wall Outlet.

3. Once these connections have been made, check the status of the two Red LED Lights.

   → If both LED Lights are ON, all circuits are properly functioning and the battery is charging.
   → If both LED Lights are ON, but moving the Battery Charging Cable causes the DIGIT-grip Device LED Light to flicker, the Cable is defective and the Battery is only charging intermittently. The Battery Charging Cable needs to be replaced.
   → If the Adapter LED Light is ON, but the DIGIT-grip LED Light is OFF, the AC power is on, but there is a problem somewhere in the circuitry and the battery is not charging.
   → If both LED Lights are OFF, no power is coming from the AC Wall Outlet.

Switching between Test Modes —

EZ and Normal

1. **TO DETERMINE THE ACTIVE TEST MODE:**

Press the [ON SEL] Button to turn the Device on. Following the device self-test and a display of the calibration value:

→ If [P1] displays, the Device is in EZ MODE.

→ If [P1L] or [P1R] displays, it is in NORMAL MODE.

2. **TO SWITCH FROM EZ TO NORMAL MODE:**

The Device displays P1 indicating it is in the EZ Mode.
Press and hold the [ON SEL] Button.
The Device will reset and a [P1L] or [P1R] will appear.
Release the [ON SEL] Button.
The Device is now in the Normal Mode.

3. **TO SWITCH FROM NORMAL TO EZ MODE:**

The Device displays P1L or P1R indicating it is in the Normal Mode.
Press and hold the [ON SEL] Button until the Display moves through the entire patient sequence and [P E] appears on the Display.
Release the [ON SEL] Button.
The Device is now in the EZ Mode.

!! ***NOTE:*** **To verify the Active Mode at the time the Device is turned On [and the Display is 00], or after switching Modes, press the [MR] Button.**

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THE EZ MODE —

DESCRIPTION

The EZ Mode supports IMPULSE (squeeze and release) test protocols. It provides the ability to save and recall the Average of the three highest peak scores generated, the actual peak scores that make up the Average, and the Coefficient of Variation (expressed as a percentage) between the three peak scores. As many trials as necessary may be taken. The program automatically averages the three HIGHEST peak scores.

The design of this EZ Mode program allows for storage of test data for ONLY ONE patient at a time. The program will automatically overwrite old data with new each time the Averaging Feature is activated [by pressing the MS Button].

The EZ Mode is designed to provide a quick and easy method for testing patients. For a permanent record, the data must be manually recorded at the time it is recalled – AFTER Averaging – and – BEFORE testing the next patient.

INSTRUCTIONS FOR USE

Press the [ON SEL] Button. A diagnostic routine checks the device calibration and battery condition. When the diagnostic routine is completed, and the device passes the self-test, it will first display the calibration value, then the Mode indicator and finally [00] indicating it is ready for use.

If the device is in the EZ Mode [P1], you are ready to begin testing. If it is in the Normal Mode [P1L or P1R], switch to the EZ Mode [see instructions on page 4].

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THE EZ MODE —

Properly install the Handle at the selected Position (1–5). Be certain that the Blue Safety Pin is installed. Place the device in the patient's hand to be tested with the LCD Display facing the evaluator. Review the test protocol with the patient.

Instruct the patient to exert maximum force and release. The peak grip score will display on the LCD Display for 5 seconds.

Wait for the Display to return to [00], then instruct the patient to once again exert maximum force and release. The peak grip score will again display. Repeat this process for as many trials as desired.

When testing is completed, press the [MS] Button. The program will automatically Average the three highest peak scores.

To review the stored data, press the [MR] Button. Each time you press and release this button, the LCD will display the stored data in the following order:

>	**P1**	**Highest Peak Score**
>	**P2**	**Second Highest Peak Score**
>	**P3**	**Third Highest Peak Score**
>	**AV**	**Average of the three above Peak Scores**
>	**CV**	**Coefficient of Variation between the three Peak Scores (in %)**

The data can be recalled as many times as desired by following the above procedure. However, the data for any given patient will remain in memory and available for recall ONLY until test data for the next patient is averaged and saved, which will overwrite the last patient's data.

!! ***NOTE:*** **Be careful to Average your data prior to attempting to recall it for review. Pressing the [MR] Button BEFORE Averaging the data will result in it being lost from memory.**

THE NORMAL MODE —

DESCRIPTION

The Normal Mode provides the ability to store and recall up to 18 tests (9 patients – left and right side). This program stores ONLY the AVERAGE of the three highest peak scores generated. The individual scores comprising the Average and the Coefficient of Variation are saved but not available for recall via the LCD Display.

Data will remain stored in memory until erased using the Erase feature or overwritten with new data using the Average and Store [MS] Button.

INSTRUCTIONS FOR USE

1. Press the [ON SEL] Button. A diagnostic routine checks the device calibration and battery condition. When the diagnostic routine is completed, and the device passes the self-test, it will momentarily flash its calibration value, display [P1], [P1L] or [P1R] to indicate the Mode it is in, and then display [00].

2. If the Device is in the EZ Mode [P1 displayed], switch to the Normal Mode following the instructions on page 4. If the Device is in the Normal Mode [P1L or P1R displayed] you are ready to begin testing procedures.

3. Properly install the Handle at the selected position (1–5) following the instructions found on page 2. Place the Device in the patient's hand to be tested so that the LCD Display faces the evaluator. Review test protocols with the patient.

ICD

THE NORMAL MODE —

4. Instruct the patient to exert maximum force and release. The peak grip score will display on the LCD Display for 5 seconds.

5. Wait for the Display to return to [00], then instruct the patient to once again exert maximum force and release. The peak grip score will again display. Repeat this process for as many trials as desired.

6. When testing is completed and the Display has returned to [00], press the [MS] Button. The program will automatically Average the three highest peak scores. The test designation (i.e. P1L) will display to confirm which data is being averaged and saved. The Average will display next, indicating the process is complete. The LCD Display will then return to [00], and the program automatically advances to the next test designation (i.e. P1r).

!! ***NOTE:*** **The automatic sequence for the Test Designations are:**

P1L: Patient 1 – Left Side
P1r: Patient 1 – Right Side
P2L: Patient 2 – Left Side
P2r: Patient 2 – Right Side ***
P9r: Patient 9 – Right Side

7. If the Test Designation Symbol (i.e. P1L) blinks when the [MS] Button is pressed, it is an indication that the test data previously stored for a patient using the same Test Designation is still in memory. Continue to press the [MS] Button until the blinking stops and the new Average displays. Old data is now overwritten and the new Average is stored in memory. The display will return to [00], and the program automatically advances to the next Test Designation, ready to commence the next test.

8. Averaged test data for any Test Designation will remain in memory until erased using the ERASE feature or overwritten with new data using the [MS] feature.

THE NORMAL MODE —

9. If patient data in memory is recalled out of sequence, it may affect the automatic advancing of the Test Designation. If you recall memory for a patient out of sequence, before testing the next patient, verify the Test Designation is correct to avoid inadertently testing two patients in the same designation. To verify the Test Designation, press the [ON SEL] Button.

10. This program facilitates moving through test designations in the following ways:

    Move forward by applying Repeated Quick Touches to the [ON SEL] Button. Each Quick Touch will advance one sequence (P1L, P1r ... P9L, P9r).

    Move forward by applying a Sustained Touch to the [ON SEL] Button. The program will advance in following sequence: (P1L, P2L ... P9L).

    Move backward by applying Repeated Quick Touches to the [MR] Button. The program will move in reverse in the following sequence: (P9L, P9r ... P1L, P1r).

11. If you are at P9r, return directly to P1L by pressing the [ON SEL] Button.

12. To globally erase all data stored in memory, simultaneously press the [MS and MR] Buttons. Flashing EEEE will display. Continue to press both Buttons until the flashing stops (about 5 seconds). All data will then be erased from memory.

!! ***NOTE:*** **The Quick Chart provided with the DIGIT–grip Device includes a Table describing all functions of the three LCD Buttons. This Quick Chart is reproduced on Pages 13 and 14.**

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NK DIGIT–grip QUICK CHART

E–Z Mode Operating Instructions

1. **Press SEL to turn the Device on. Select the Handle Position.**
2. **A diagnostic routine checks the device calibration and battery condition. When the diagnostic routine is completed and the Device displays P1 and then 00, begin patient testing.**
3. **Instruct patient to hold device with display facing toward evaluator. Instruct to exert maximum force and release. The peak will display for 5 seconds and then return to 00 indicating it is ready for the next trial. As many trials as desired can be taken.**
4. **Press MS to average the test results. The three HIGHEST peaks will be saved and averaged.**

WARNING: ***Be sure you have averaged your data before pressing MR as instructed in No. 5 below. Pressing MR before MS will erase the patient data just taken.***

5. **Press MR to recall the test results in memory. The device will display data in the following order:**

   P1 – Highest Peak
   P2 – 2nd Highest Peak
   P3 – 3rd Highest Peak
   AV – The Average of the above 3 Peaks
   CV – The Coefficient of Variation between the 3 Peaks (%).

WARNING: ***The design of the EZ Program allows for automatic overwrite of old data with new when the MS (Storing and Averaging feature is used.***

For help contact:

NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, MN 55441

Normal Mode Instructions (See Reverse Side)

1. **Press SEL to turn Device on. Select Handle Position.**
2. **After the diagnostic routine, if P1L or P1R displays, followed by 00, the device is ready to commence testing in this Mode.**
3. **Instruct patient to hold DIGIT–grip with display facing away from patient and review test protocol.**
4. **Instruct patient to exert maximum effort and then release. Upon release, fingers should be removed from the front handle.**
5. **The peak grip score will display for 5 seconds and then return to 00. Once the display is showing 00, proceed to the next trial.**
6. **Take as many trials as desired, following the same procedure.**
7. **When the display returns to 00 after the last trial, press the MS Button to average the 3 Highest Test Scores.**
8. **Recall saved Averages by pressing the MR Button.**

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Selection Buttons – for use with Normal Operating Mode

SEL [Quick Touch]	Turns on Device. Initiates automatic self–test and calibration routine. If self–test passes, the calibration value will display momentarily. The display will then return to 00 and is ready for testing. One quick touch to SEL displays the current patient number/side.
SEL [Repeated Quick Touches]	SELECTS patient number [and left or right hand] in ascending order [e.g. P1L, P1r, P2L, P2r].
SEL [Sustained Touch]	SELECTS patient number only in ascending order [e.g. P1L, P2L, P3L].
MS [Quick Touch]	Averages the three highest test scores and stores average. The average will display indicating storage is complete, and the display will return to 00. The Device has automatically advanced to the next test [e.g. from P2L to P2r, from P2r to P3L]. If display is blinking, see MS [Sustained Touch].
MS [Sustained Touch]	If blinking, indicates previously stored data is still in memory. To clear old data and store new, sustain touch until blinking stops. Data is now saved and the patient number and side are automatically advanced.
MR [Quick Touch]	Displays first the current patient's left hand stored data.
MR [Sustained Touch]	Recalls patient number [left or right] in descending order along with stored data [e.g. P3L, data, P3r, data].
SEL MS [Sustained Touch]	When pressed simultaneously, toggles between kilograms and pounds. [The green light indicates the current setting.]
MR MS [Sustained Touch]	When pressed simultaneously and held for five seconds, erases all stored data. [Press both buttons until the flashing EEEE has stopped.]
*	Resets the LCD Display.

Features

1. The device battery will operate for nine hours of constant use. When the device is used daily, it is recommended that the battery be charged, by using the battery charging cord provided, at the close of each day to assure the battery remains fully charged.
2. ***SWITCHING BETWEEN EZ AND NORMAL MODES:*** When the Device is turned on, it will display P1 after the calibration routine if it is in the EZ Mode. If in the Normal Mode, it will display P1L or P1R.
   - *Switch from EZ to NORMAL:* Press the SEL Button. The Device will reset. Release the SEL Button. The Device has now changed from EZ to Normal Mode.
   - *Switch from NORMAL to EZ:* Press and hold the SEL Button until the Display moves through the entire patient sequence and [P E] appears. Release the SEL Button. The Device is now in the EZ Mode.
3. Once the data is stored in memory, it will not be lost because of battery failure or loss of power.
4. If the automatic self–test fails, CAL will flash and the display will go blank. Do not continue testing. Call the NKB help line, as some type of failure has occurred.
5. When the battery is low, BAT will flash on the display. If this occurs, recharge the Device for at least 8 hours before testing on the battery.
6. To conserve battery power, the Device has an automatic shut off feature. If no button has been pushed or no squeeze over 1 KG [2 LB] has occurred within 70 seconds, the device will shut off and any unsaved data is lost. If this occurs, to continue testing, press SEL to turn the Device back on.

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