DynX®
User Manual

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REGULATION REFERENCES:

Applicable standards:

General: Medical Device - 93/42/EEC and revised version

Risk Analysis: Application of risk management to medical devices - CEI EN 14971:2007

Labelling: Graphical symbols for use in the labeling of medical devices - CEI EN980:2008

Electrical Safety: Safety requirements for electrical equipment - CEI EN 60601-1:2007

Electrical and electronic equipment waste: Waste electrical and electronic equipment (WEEE) Directive - 2002/96/EC

EMC compliance: Electromagnetic Compatibility - CEI EN 60601-1-2:2007

Classification of the device:

DynX® is classified as a CLASS I medical device (Directive 93/42/EC).

Symbols


Symbol referring to the manual


Symbol indicating the conformity to Directive 2007/47/EEC


The presence of this symbol in a paragraph stands for a warning


Symbol recommending the recycling of polluting components


Symbol indicating correct disposal of the exhaust product (pursuant to Directive WEEE)

CHAPTER 1 GENERAL INFORMATION

SAFETY WARNINGS

CAREFULLY READ THESE INSTRUCTIONS AND KEEP THEM FOR FUTURE REFERENCE

- Avoid use of the DynX® device under conditions of extreme heat, extreme cold, dust, moisture, solvents and oils.
- Do not place it on unstable surfaces. The instrument may fall and be seriously damaged.
- Avoid storage in direct sunlight for long periods, or in areas of extreme heat that may damage the instrument case and handles.
- Do not immerse the DynX® device in any liquid or subject it to steam sterilization. Clean the exterior with a soft damp cloth using mild detergent as a solvent.
- Do not use liquids on the display. Avoid use of abrasive paper product when cleaning.
- Do not try to repair the device: no user-serviceable parts inside. Maintenance and repair must only be performed by qualified technical personnel.
- Replace the 9 Volt battery as necessary. A display will appear if the device detects a low battery condition.

CAUTION

If the user detects any unusual characteristics in the performance of the product, discontinue use of the DynX® and contact the Distributor.

IMPORTANT NOTE:

This product is designed for a maximum load capacity of:

200 total pounds resulting from a balanced application of 100 pound maximum forces to each end of the front handle

Exceeding these load limits (200 pounds total or 100 pounds on each end of the front handle) may permanently damage the electronic beams and will not be covered under the warranty.

DynX® is a registered trademark of MD Systems, Inc.

Covered by US Patents 6.962.569 and 7.448.265. Other patents applied for Canadian Patent 2.501.427; European Patent 1.578.248

WARRANTY TERMS AND CONDITIONS

This instrument is warranted to be free from manufacturing defects for a period of 12 months from the delivery date specified in the delivery document, test document or tax document.
During the warranty period Akern shall repair or replace the defective instrument, at its own discretion.
In case, upon inspection, there is evidence of product damage, which was not caused by faulty material or workmanship, Akern will notify customers of this finding and will request further instructions on how to proceed.
Akern will not be responsible for the loss of archived data stored in the DYNX® products that are returned for service.
The warranty is valid for products used within the guidelines described in this User's Guide.

The warranty does not cover:

- damages to instrument caused by accidental events;
- damages to third parties resulting from careless or improper use of the instrument by the user.

The guarantee is automatically void in the following cases:

- malfunctions, breakages or damages resulting from the non-observance of the instrument use and maintenance instructions;
- malfunctions, breakages or damages resulting from careless or improper use of the instrument;
- malfunctions, breakages or damages resulting from interventions on the instrument by the user (repair attempts; modifications).

Akern is liable for damages due to its fault or negligence up to a maximum corresponding to the list price applicable on the date of the purchase.

Akern declares that the content of this manual is accurate; however, it reserves the right to modify it in the following editions, without notifying changes to users in possession of the current edition.
If the user finds some inaccuracies, it is recommended to contact the Distributor.

INTENDED USE

DynX®™ is a device designed for use by professional technicians and therapists in measurement of hand grip strength conditions using Grip Test functions built into the product. As with any such device, these functions and the device itself should be thoroughly studied and understood before use.

FEATURES AND SPECIFICATIONS

DynX®™ hand dynamometer provides clinicians a means of performing a series of very accurate hand grip strength measurements and training efforts. Sequences of grip measurements such as Max Test and Rapid Exchange Test yield automatic calculation of Average, Deviation and Coefficients of Variation related to the series of measurements. Endurance Test measures time during which a specified Target Force can be applied to the device, and then measures strength decay as a function of time after the Target Force can no longer be maintained and until a point of fatigue is reached. All measurements are stored in memory. DynX® therapy regimens may utilize automatically established protocols or customized protocols yielding score performance. The product's digital display provides menu driven instructions for selecting product configurations, types of measurements, training options and user guidance. DynX® devices measure the user's maximum grip strength and store this grip strength into memory as a means of establishing target forces during therapy session. A high-speed clock in the DynX® device identifies how well each user complies with the training program efforts and rest periods. At the conclusion of a training session, the DynX® device evaluates the quality of the training and scores the effort on a scale of 0% to 100% so that the user or their clinician can evaluate how well training was accomplished. All set-up parameters and scores are stored at the conclusion of a therapy session, so that results may be later analysed. The built –in clock informs users when to begin or end efforts and rest periods using visual instructions on the face of the instruments with an audible tone. During therapy sessions, training targets are indicated by a bar graph on the left side of the digital display. The right side of the digital display shows the current score and time remaining for the effort. Time counts are shown in seconds remaining for each effort. Grip widths available for measurement and therapy range from 1-7/8 inches to 2- 3/8 inches in ½" inch increments. Grip width considerations include comfort and range of motion for each user. Therapists should decide which widths are appropriate for each patient and adjust the width accordingly. The DynX® is turned off if unused for 5 minutes.

PRECAUTIONS

There are minimal considerations for Limitations and Precautions in these applications.

Individuals suffering from acute arthritis or those affected with carpal tunnel limitations should consult their physician for recommendations on suitability of this product before use. Individuals with injuries, impairments or disabilities to the fingers, hand, wrist or arm should not operate the instrument or do so only after complete examination and appropriate testing by a physician and/or physical therapist. User limitations, anatomically or physiologically, which prevent them from performing a true MAX, should be reason to stop using this device.
It is very important that the DynX® user squeeze the device with the absolute maximum possible force to set the MAX's so that the desired conditioning is achieved. If lower MAX's are used, the training may not produce optimal results.

Unless the DynX® device is used under the close supervision of a physician, anyone who has experienced a known cerebral aneurysm or a severe diabetic retinopathy or exhibits symptoms of these conditions or is limited from exercise by a cardiologist should NOT perform any exercise,

Only a patient's own MAX should be used to set target force levels.
Each person must establish his or her own Maximum Voluntary Contraction (MAX) to implement the proper training target force. Using someone else's MAX will make the training ineffective or could cause unnecessary stress and fatigue of the user during the training sequences.

CHAPTER 2 USE OF DYNX®

DESCRIPTION

LIQUID CRYSTAL DISPLAY

An easy to read reflective liquid crystal display guides users through the exercise instructions, combined with audio cues. Operation temperature is -20°C to +50°

BATTERY COVER

For easy access to the 9VDC Alkaline high capacity battery

MENU BUTTON

Allows the user to access a list of functions provided by the device

ON AND SELECT BUTTON

Activates the various modes of operation and can be used to turn the device OFF in advance of its automatic turn-off sequence, when it is not used for 5 minutes

FRONT HANDLE

Designed to comfortably fit the palm or fingers of the hand and covers the electronic load cells that measure the force being applied (0.1 pounds or 1.0% force accuracy) Attaching a Grip Extender expands the grip width by ½ inch.

COM PORT

Provided to interface DynX® to computers and similar compatible devices for data access and remote monitoring

REAR HANDLE

Designed round and smooth to maximize the user's comfort and capability to expand the grip width by attaching a Grip Extender.

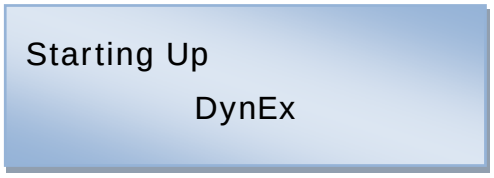
DURABLE PLASTIC SHELL

Provides high-impact protection for long life, durability and ease of maintaining instrument cleanliness. The device weighs 0.7 pounds or 0.3 kilograms.

GRIP EXTENDER

May be attached to either or both handles to provide adjustable grip widths from 1-7/8 inches to 2—5/8 inches which are the commonly used widths (positions 2, 3 and 4) on Jamar-type hydraulic hand dynamometers.

TURNING DynX® ON

	Press *Select* push-button. At turn-on the display will identify the model as DynX®. DynX® performs Grip Test, Grip therapy and functions.
	DynX® Menu selections include: - Grip Test (hand dynamometer mode) - Grip Therapy (grip strength training mode) - Configuration (Configuration mode) *These alternatives are available by pressing the "menu" key sequentially. Press the "select" key to activate the desired item*

CONFIGURATION SETTINGS

	**Set Units** DynX® may be configured for operation in English (Pounds) or Metric (Kilogram) measurements. *Menu* to toggle between each alternative *Select* to acknowledge a preference.
	**Set Tone** To enable and disable the audible tone generator: Audible Tone, Yes (Y) or No (No) *Menu* to toggle between each alternative *Select* to acknowledge a preference.
	**Archive Erase** To erase the data already stored in DynX® memory archive: Archive Erase, Yes (Y) or No (No) *Menu* to toggle between each alternative *Select* to acknowledge a preference.

After setting the desired configuration items, the display will be restored to Menu – Configuration. Return to Grip Test by pressing the Menu key.

CHAPTER 3 DYNAMOMETER FUNCTION

Grip Test provides three DynX® modes:

1. Maximum Test
2. Endurance Test
3. Rapid Exchange Test

Press *Menu* to scroll the available alternatives.
Press *Select* to the desired item

1.MAX TESTS

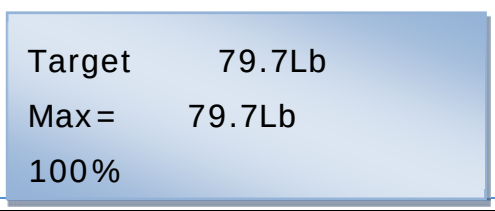
Max test is typically accomplished in one hand, although it can be used for comparison between hands.

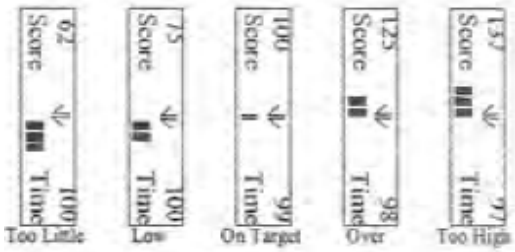
	Squeeze to start measurement
	Press *Select* to accept as a valid measurement and store the data as part of a series of measurements.
	Squeeze again to repeat the measurement.
	Statistics are generated for the measurement sequence. These calculated statistics include Average, Standard Deviation and Coefficient of Variation between measurements after the *Select* key is pressed following each stored Max measurement. *Select* to go to next measurement
	Each Max Test may include **up to** 10 measurements in a sequence. At the end of any number of sequential measurements: *Select* to review each Max measured in the sequence

	Press *Menu* to*:* - Restart Max Test - Review Last Data This function is also available from the non-volatile data archive when this Max Test mode is again selected following turn-off. - Previous Menu

2. ENDURANCE TEST

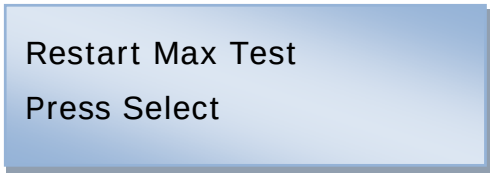
The Endurance Test evaluates the time during which a specified Target Force can be applied to the device by a test subject and to measure decline in strength as a function of time after the Target Force can no longer be maintained, until a point of fatigue is reached, concluding the test when pressure on the handle is released. The Endurance Test measures time (in seconds) during which grip strength can be sustained at or above the Target Force level, then collects time markers each time the strength measurement decline by 10% of the Target Force until the test subject releases pressure on the DYNX® handle at 0% of the Target Force. Target Force is defined as a percent of Maximum Force (Max) of the muscle group measured before the test is conducted.

	**Test set up** *Select* to set Target Force
	The patient is asked to perform a maximum hand-grip effort for the hand to be evaluated. This is called a Max effort. Squeeze to set Max effort.
	Squeeze again to repeat the measurement.
	Press *Select* to accept as a valid Max effort parameter.
	Press the *Menu* key to set the Target Force by selecting a % Max target prior to initiating the test. Each hit on the *Menu* key adjusts this target by 10% increments.

	Press *Select* to lock in the Target Force desired
Target= 63.7Lb Press Select	The Display shows %Max and the target force amount (in Lb or Kg) when the Target Force is selected. *Select* to perform Endurance Test *Menu* to return to Target Force setting
Hold on Target Squeeze	**Performing Endurance Test** Apply pressure on the DynX® handle.
	Elevate this pressure quickly, until the bar-graph on the display disappears in the centre of the display and a Target Force "arrow" appears. Reaching this Target level of applied pressure on the handle starts a count-down clock. A "Score" at the top of the display shows 100 when the target force is achieved and continues to display instantaneously the % of Target Force being applied to the handle. Time count at bottom of the display indicates the number of seconds elapsed since the Target Force was reached. An audible tone occurs each time the applied force on the handle drops by 10% increments

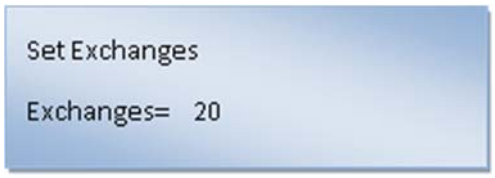
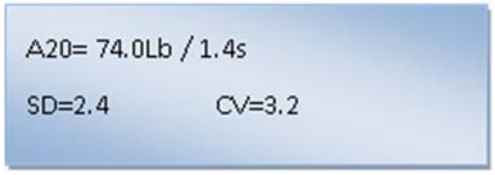
IMPORTANT NOTICE: Do not allow the applied force below the 100% level until it is no longer possible to maintain that level of pressure to the handle, and then continue applying a maximal effort for the remainder of the test, to a point of fatigue.

M= 79.7Lb 100% T= 63.7Lb 10.2s	**Data Review** The test is completed when the test subject releases all pressure on the handle. M = Max effort T = Target Force The display shows time in seconds (s) held at the Target Force level %

 	Press *Select* key sequentially to review the time markers which note elapsed time upon reaching 90% T, 80% T, 70% T etc. until 0% T is reached. This review shows the time in seconds at which each particular % Target is crossed
	Press *Menu* to: - Restart Endurance Test - Review Last Data - Return to Previous Menu

3.RAPID EXCHANGE TEST

The Rapid Exchange Test measures hand grip strengths comparatively in Right and Left Hands during Rapid Exchanges, yielding automatic calculation of Average, Deviation and Coefficients of Variation related to the series of measurements.

	Test set up Set Cycle Time: Press the *Menu* key to toggle between the Exchange rate of 1.5 or 0.8 seconds. Press *Select* to lock in the Exchange rate desired
	Set Exchanges: Press the *Menu* key to set Exchanges at 10 or 20 Press *Select* to confirm the desired option
	Start measurement with a Right Hand Squeeze. The R-E sequence begins when pressure is first applied.
	At conclusion of the Right Hand Squeeze (Max 1) a 1.5 or 0.8 seconds time-out will be concluded with an audible tone signaling the next Left Hand squeeze should be done (Max 2) . This sequence of Squeeze and Tone will continue until the end of the 10 or 20 efforts.
	Statistics are generated for the measurement sequence. These calculated statistics include: - Average (A) - Actual Cycle Time in seconds between exchanges (s) - Standard Deviation (SD) between all measurements - Coefficient of Variations (CV) between all measurements
	Pressing *Select* provides a detailed review of each effort and the grip strengths measured compared to Average for the 10 or 20 measurements.

	Press *Menu* to: - Restart Rapid Exchange Test - Review Last Data This function is also available from the non-volatile data archive when this Rapid Exchange mode is again selected following turn-off. - Return to Previous Menu

CHAPTER 4 GRIP THERAPY

Grip therapy uses a series of isometric contractions, which can be specified by the therapist in magnitude of the effort , duration of the effort, length of rest periods between efforts, and repetition of the efforts Grip therapy modes are designed to increase or restore handgrip strength. Grip therapy can be selected between fixed or stepped therapy regimens.
DynX® provides two different but similar protocols to perform isometric therapy for patients who can benefit from this form of grip therapy. Pressing the "select" key when in the grip therapy display, provides two "menu" key options called "fixed therapy" or "stepped therapy". Both isometric therapies are based on a patient's maximum grip strength (Max) as measured in the arm requiring strengthening or rehabilitation.

1.FIXED THERAPY

This isometric therapy is provided to strengthen handgrip muscle groups by establishing a specific level of effort proportionate to a patient's existing grip strength. Each precisely timed effort is spaced by a rest period to minimize fatigue prior to resuming the effort.

All therapy sessions begin with establishing a maximum strength measurement. The therapist presses the "select" key to confirm it is a good measurement.

Fixed Therapy Press Select	*Press Select*
Do Max 0.0 Kg Squeeze Hard!!!	All therapy sessions begin with establishing a maximum strength measurement.
Max 1 79.7Lb or Squeeze Again	Press select to confirm it is a good measurement or squeeze again to perform another measurement.
Set Max 79.7Lb Press select	This measurement is used to set the Target Force as a percent of the Max to be used in the therapy regimen. The nominated target force is 50% of max.

This percentage can be adjusted to higher or lower value in 10% increments by pressing the menu key.

Pressing the select key locks in the preferred target force, then nominates the number of repetitions

Nominated values for fixed therapy

Pre-programmed set points for fixed therapy utilize the following combination of % max, reps, effort and rest times. As % max is established , the reps, effort and rest times values conform to those in the table unless they are modified by the clinician. These values are known to be safe for persons with hypertension to minimize blood pressure elevation. Issues pertaining to other cardiovascular disease states should be considered for each patient before pursuing this isometric exercise regimen or any other form of exercise training.

Max %	**10**	**20**	**30**	**40**	**50**	**60**	**70**	**80**	**90**	**100**
# Reps	4	4	4	4	4	4	4	4	4	4
Effort	120’	120’	90’	60’	45’	15’	12’	10’	5’	3’
Rest	60’	120	120’	120’	120’	120’	120’	60’	60’	30’

Clinicians may reset any of these parameter. The blinking items on the display identifies which value (Rep, hold or rest) that can be accepted by pressing the “Select” key or modified using the “Menu” key.

2.STEPPED THERAPY

Press the select key to start the stepped therapy set up. Steps provided in this particular therapy vary between 1 and 5- steps. The following matrix illustrates the % of max strength used in the protocol.

Steps	1	2	3	4	5
1st step as % Max	20%	40%	60%	80%	100%
2nd step as % Max		20%	40%	60%	80%
3rd step as % Max			20%	40%	60%
4th step as % Max				20%	40%
5th step as % Max					20%

This action provides a display, which describes the need to define a patient's maximum strength (max) and establish the number of steps and reps in the regimen. Press the select key to initiate max measurement.

Therapists then define the number of steps desired and the number of repetitions to be repeated during each therapy session. Press the menu key to cycle through each of the Step and Rep options as they blink.

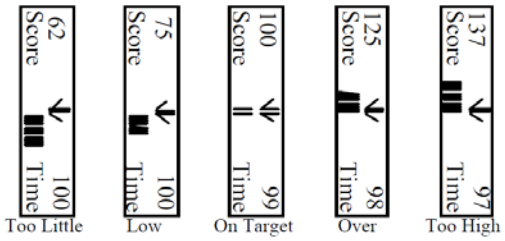
Do Max 0.0 Lb Squeeze Hard!!!	One or more (up to 10 Max) measurements may be done to establish the set point for a patient's Max. Press the select key to set the max.
Max 79Lb 1 Step 4 Rep	Press the select key to advance from setting Steps to set Reps..
Start Therapy Press select	Once all parameters are established, the clinician can elect to start stepped therapy by pressing the menu key to active the session

20% Max	40% Max	60% Max	80% Max	100% Max
120 sec. Effort	60 sec. Effort	15 sec. Effort	10 sec. Effort	5 sec. Effort
120 sec. Rest	120 sec. Rest	120 sec. Rest	60 sec. Rest	30 sec. Rest

The display requests activation of stepped therapy by pressing the select key. If the menu key is pressed, the display will advance to the beginning of the programming sequence of stepped therapy parameters.

PERFORMING THE GRIP THERAPY

Both fixed and stepped therapy are conducted in the same manner and will be discussed in this section. Activating the therapy begins with pressing the select key at the end of each of the set-up sessions.

Hold on Target Squeeze	Guidance is given by the next display, indicating a need to squeeze the handle and to “hold on target” such that the bar-graph on the display
	When the target force level is achieved , the word “Score” is shown on the top of the display and the word “Time” appears in the bottom of the display. Above each word is a number representing the performance. Score on a scale of percentage of effort being exerted, and countdown Time in seconds remaining for that effort. Shown are examples of how the display would appear under different performance levels
Score is now 92 Rest Time 120 3 Efforts to go Rest Time 10	At the end of each effort the display changes to rest Time in seconds and shows an accumulative Score as a percentage of the total effort desired. At the end of the first effort, this score is total for the first effort. At the end of the second effort, it is the Sum of scores for the first and second efforts, etc. During the rest periods, the top line alternates “Score” and “Efforts to go”
Suggestion: after completion of each hand grip training , during the rest period, it is recommended to slowly and gently, rhythmically stretch the hand that was used for the effort, by opening the hand with full extension of the fingers, then closing the fist, but not squeezing. These gentle motions, repeated 8 or 10 times about once per second, or even for a longer time during the rest period will help to stretch out muscles that tightened somewhat during the contraction and will aid blood circulation through the muscles.	
Final Score is 90 out of 100 Squeeze	At the conclusion of each therapy session the display shows how completely the therapy was conducted by using a “Final score”
Grades & scores: the DynX®® device evaluates how well each user performed their grip therapy training effort. At the conclusion of the training session, prior to turn-off, DynX® will provide a measure of this performance on a scale of 0 to 100, with 100 being a perfect score.	

A typical score would appear as: “Final score is 92 ot of 100”

This score is translated into a statement of performance , offering feedback:

TURNING DYNX® OFF

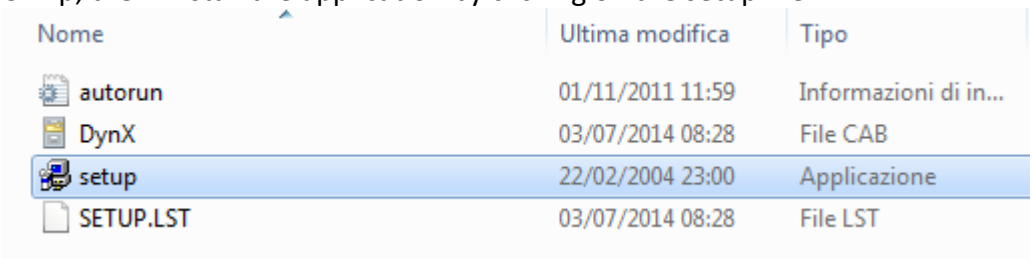
To turn DYNX® off press *Select* for 5 seconds. The DYNX® device is equipped with an automatic turn-off function to save battery life, if the device is unused for a period of 5 minutes.

CHAPTER 5 : PC INTERFACE

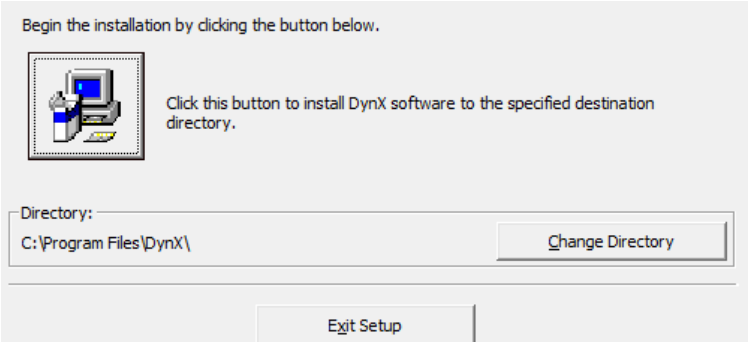
Download the software from www.akern.com, SOFTWARE menu > DOWNLOAD AREA > DYNX® HANDGRIP SOFTWARE . Log –in information are:

Username: clientiakern
Password: akern123

Unzip, then install the application by clicking on the setup file.



Follow the instructions displayed.

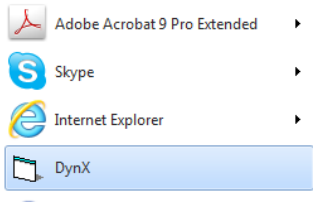


Once the setup has completed, connect the DYNX® to the USB port through the cable supplied along with the device. switch on the handgrip pushing the “select/ON” button

USB / RJ11 connection cable for DYNX®

When the USB cable is first plugged in, there will be an installation of drivers that takes place: this may take a few minutes, and should only occur the first time the cable is used with that PC.

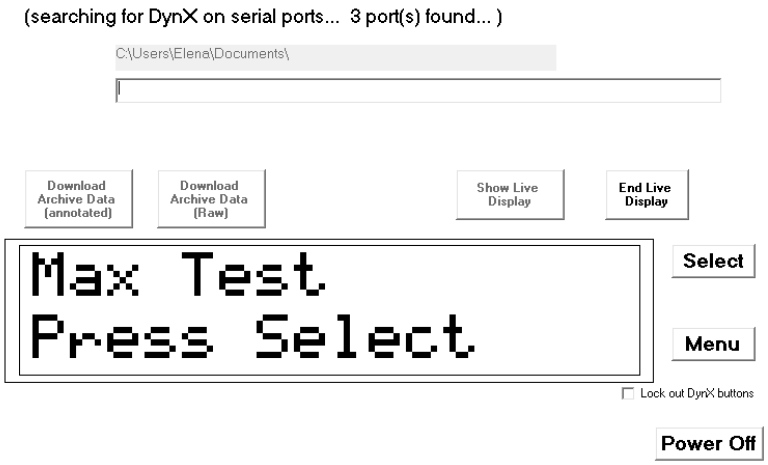
Run the software from the Start menu > DynX®



The PC will automatically scan the available communications ports, detect a powered on DynX®, and establish a connection.
From there, users can chose

- to download the archived data from the device,
- to show a live copy of the DynX® screen.

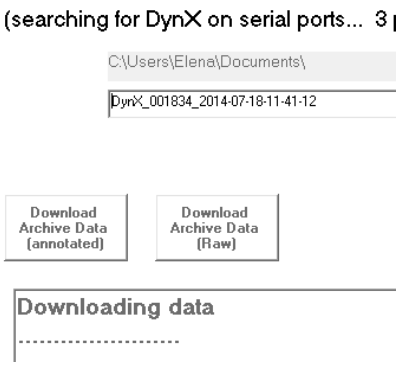
LIVE DISPLAY
Live display feature allows the user to monitor the DynX® screen from the PC.



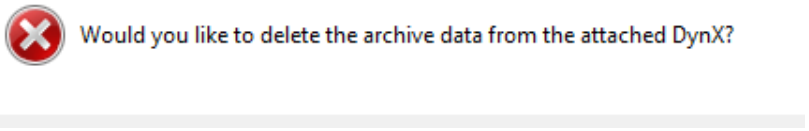
DATA DOWNLOAD

The DynX® internal memory can store the average values, the standard deviations and the coefficient of variation of each test.

The Download Archive Data (annotated) icon and the Download Archive Data (Raw) icon allows the user to download the data stored in the DynX®



DynX® database can be deleted when the database download has finished.



Download Archive Data (annotated) feature allows to create one excel file for each type of test stored:

Download Archive Data (Raw data) feature allows to create one single coma separated excel file for all the data stored.

NOTE:

Ms Windows 7™ and Ms Windows 8™ operating systems are able to install automatically the best driver for the USB or RS 232 converter only if connected to the internet.

CHAPTER 6 ADDITIONAL INFORMATION

BATTERY INSTALLATION

Before use install the 9 Volt Battery as follows:

1. Remove the product from its plastic bag
2. Identify the battery door and the latch pad
3. Press down the latch pad with the thumb to disengage the latch
4. Slide the battery door away from the front of the case
5. Carefully remove the battery connector from the back of the battery enclosure
6. Snap the battery connector onto the battery terminals, being careful to match them to the proper polarity (note that the connector can only be snapped onto the terminals when the polarity is correct)
7. Slide the connector end of the battery into the battery enclosure first, making sure the tab on the connector is pointing outward (+ terminal is at bottom of the enclosure)
8. Carefully slide the battery and its attached connector into the battery compartment
9. Install the battery door by sliding it inward until it is latched, making sure the wires or battery do not interfere with the latch mechanism.

MAINTENANCE INSTRUCTIONS

The DYNX® device is mechanically and electronically rugged, built to withstand normal use in clinical, home, office, public or private transportation environments.

The electronics are digital and require no regular maintenance except for periodic battery replacement. Unless damaged by unusual stresses, the electronic load cells require no specific attention. The case of the instrument is made bydurable materials that are designed to withstand ambient heat or cold typical of household environments, and normal cleaning.

Do not immerse the DYNX® device in any liquid or subject it to steam sterilization. Clean the exterior with a soft damp cloth using mild detergent as a solvent.

Do not use liquids on the display. Avoid use of abrasive paper product in cleaning.

The only anticipated regular maintenance items are cleaning and battery replacement.

TECHNICAL SUPPORT AND SERVICE

The instrument does not include any user-serviceable parts.

In case of maintenance or replacement of the instrument, follow this procedure.

BEFORE shipment, please contact the Akern Technical Department by phone, fax or e-mail to obtain the necessary return authorisation, to agree a correct shipment of the material and to estimate the return times. Use original package for the shipment, which is suitable for air and/or surface transport. Also include a document with the description of the detected malfunction and the name of the public body or private person, complete with all phone numbers / e-mail addresses.

Shipping address:

Akern srl Via Lisbona ,32

I-50065 Pontassieve (FI) ITALY

Fax: +39.055.8323516

www.akern.com

E-mail: akern@akern.com

REFERENCE VALUES

MEAN and SD of HGS (kg) for healthy men and women

Men				Women			
Age	right	left	BMI	Age	right	left	BMI
20 to 29	47(9.5)	45(8.8)	26.4(5.1)	20 to 29	30(7)	28(6.1)	25.1(5.8)
30 to 39	47(9.7)	47(9.8)	28.3(5.2)	30 to 39	31(6.4)	29(6)	27.3(6.8)
40 to 49	47(9.5)	45(9.3)	28.4(4.6)	40 to 49	29(5.7)	28(5.7)	27.7(7.7)
50 to 59	45(8.4)	43(8.3)	28.7(4.3)	50 to 59	28(6.3)	26(5.7)	29.1(6.4)
60 to 69	40(8.3)	38(8)	28.6(4.4)	60 to 69	24(5.3)	23(5)	28.1(5.1)
70 +	33(7.8)	32(7.5)	27.2(3.9)	70 +	20(5.8)	19(5.5)	27(4.7)

Adapted from: *Massy-Westropp et al.: Hand Grip Strength: age and gender stratified normative data in a population-based study. BMC Research Notes 2011 4:127.*

CHECK LIST

Device : DynX® Handgrip – serial number _____

Accessories:

Handles	2/
9V. battery	1/
USB/RJ11 cable 0CUSBDYN	1/
User manual	1/

Packed and checked by _____

Date _____

TECHNICAL SPECIFICATIONS

DEVICE TYPE:	Electronic Hand Dynamometer
MODEL:	DYNX®
DISPLAY TYPE:	Reflective Liquid Crystal
POWER:	9 Volt Battery
LOAD CELL ACCURACY:	0.1 Pounds (or 0.1% Force)
MAXIMUM LOAD CAPACITY	200 lbs, centre handle, 100 lbs ends of handle
GRIP WIDTH OPTIONS	Nominally: 1-7/8, 2-3/8 inches
DATA COMMUNICATION PORT	USB/RS-232
OPERATIONAL TEMPERATURE RANGE:	+5°C to +50°C
OVERALL DIMENSIONS:	
Length:	1.75 inches
Width:	3.50 inches
Height:	7.75 inches
Weight:	0.5 pounds, 0.2 kg

DECLARATION OF CONFORMITY

Legal Manufacturer: **MD Systems, Inc,**
5805 Chandler Court, Suite 2C
Westerville, Ohio 43082, USA

European Rappresentative : **AKERN**
Via Lisbona, 32/34
50065 Pontassieve (FI) ITALY

Declares, that the product

Product Name and Model: DYNX®

as described above are in conformity with the requirements of the 93/42/CEE and subsequent amendments.

Detail information:
Conformity Pathway: Annex VII
MD Classification type: Class I
MD Classification Rule: ANNEX IX, Rule 1, section 1.1
CE marking of conformity: CE

The undersigned, hereby declares that the medical device specified above, is in conformance with the Directive 93/42/EC and its revised versions, in accordance with the essential requirements of Annex I and it is manufactured compliant to technical documentation required by Annex VII Session 3.

Akern
Antonio Talluri
(President)

Attachment A:		
category	**name**	**reference**
General	Medical Device	93/42/EEC and revised version
Risk Analysis	Application of risk management to medical devices	CEI EN 14971:2007
Labeling	Symbols for use in the labeling of medical devices	CEI EN980:2008
Electrical Safety	Safety requirements for electrical equipment	CEI EN 60601-1:2007
Electrical and electronic equipment waste	Waste electrical and electronic equipment (WEEE) Directive	2002/96/EC
EMC compliance	Electromagnetic Compatibility	CEI EN 60601-1-2:2007