MAN087 Model 01165

Lafayette Hand-held Dynamometer

User Instructions





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The Lafayette Hand-held Dynamometer (HHD) is an ergonomic hand-held device used for objectively quantifying muscle strength. The test is performed with the clinician applying force to the limb of a patient. The objective of the test is for the clinician to overcome or "break" the patient's resistance. The HHD records the peak force and the time required to achieve the "break" providing reliable, accurate, and stable muscle strength readings.

The HHD also features interactive menus to allow a wide range of options such as data storage, preset test times, and force thresholds to be implemented. While powerful and versatile, the HHD is still small enough to fit comfortably in the palm of the hand. Its ergonomic design allows for both patient and tester comfort while easily conforming to testing protocols.

Features

- Designed for high inter and intra instrument reproducibility
- Three, easy to change molded plastic stirrups with pads
- Force measurements in pounds, kilograms, or Newton (user selectable)
- Measures peak force, time to reach peak force, total test time, time within selectable ranges, and the average force
- Data storage for up to 150 tests in on-board memory
- Automatic storage of data
- Measurement range 0-300lbs (136.1kg/1335N)
- Selectable test time from 1 10 seconds
- Tone to indicate start, stop, and entering within a range
- Microprocessor controlled
- Built-in stored data browsing capability
- Easy to read graphical LCD display
- Automatic shut off after 5 minutes of inactivity
- Battery indicator on LCD display
- Interactive menus allowing users to select device options
- Battery powered: (1) rechargeable lithium-ion battery
- Minimal measurement drift

Specifications

- Size: 3.16" x 5.11" x 1.6" (8.03cm x 12.98cm x 4.1cm)
- Weight: 312 g
- Range: 0-300 lbs (136.1kg) (1335 N)
- Accuracy: ± 1% over full scale or ± 0.2 lbs
- Resolution: 0.1lbs/0.1kg/0.1N(0-999.9N) / 1N(1000N-1335N)
- Battery Life: 6 hrs powered on, 30 minutes after low battery condition
- Charge Time: 80% charge => 45 minutes / Full charge => 2 hrs
- Data Storage Capacity: 150 tests
- Preset Test Length: 0.5-10 seconds; in 0.1 second increments
- 25 ms sample rate

Precautions

- When performing repeated tests, inconsistent placement of the HHD will adversely affect scores
- Extreme temperature, especially heat, may affect the values obtained.
- The HHD cannot tolerate the stress of being used as a floor scale.
- Care should be taken not to drop the HHD, as it may affect the calibration.
- Exceeding the force limit (300lbs/136kg/1335N) may permanently damage and/or invalidate the calibration of the HHD.
- Upon initial receipt of HHD, charge for 2 hours.
- Stirrup should be rotated clockwise on and off to reduce friction on O-ring.
- This device uses a Lithium-Ion battery as a power source. It is recommended that the battery
 be charged at least once every six months. Failure to periodically charge the battery may
 result in battery damage or device malfunction.

Basic Operations

The Lafayette HHD is small enough to be held in one hand and easily read. The size and weight of the HHD permit the examiner to use the same procedures and break test techniques described in the literature and taught by academic institutions without any modification of technique or positioning. The unit is simply placed between the examiner's hand and the limb being tested. The examiner's downward force is transmitted to the limb through the HHD unit. The HHD is designed for one hand operation. It can comfortably fit in the right or left hand, with settings for both dexterities. The hand is placed under the strap and around the body of the HHD. This allows easy access to the TOP buttons with the thumb. All of the other buttons are pressed using the opposite hand.

The HHD is activated by pressing the Menu/Select button. Measurements are taken by pressing the padded stirrup against the muscle being tested on the subject. The force and time data are displayed on the LCD screen. To conserve battery life, the HHD will deactivate itself when not in use for five minutes. All data on the main screen at power down is saved and will be shown when the HHD is activated again.

Function Buttons

The HHD has five function buttons that control the menus and allow the selection of options and settings.

- 1. POWER/MENU/SELECT Button: The round MENU/SELECT button is located on the bottom middle of the HHD. This is the button used to power on the device. Holding the MENU/SELECT button for 5 seconds will power off the unit. It is placed for easy access regardless of right or left hand operation. The MENU/SELECT allows you to enter into the Menu screen and select various options within it.
- 2, 3. NAVIGATION Buttons: While on the Test screen the NAVIGATION buttons are used to enlarge the graph and return back to the Test screen from the enlarged graph, or scroll though tests when in test scrolling mode. While in the Menu screen, the NAVIGATION buttons are used to navigate the various menu screens.
- **4,5. TOP buttons:** On the Main screen the TOP buttons are used to SEND, CLEAR, and START tests when applicable. On the menu screen these buttons are used to return back one screen, BACK, or return to the Test screen, TEST. These buttons can be flipped for a specific dexterity by changing the button orientation in the OPTIONS menu.



Screens

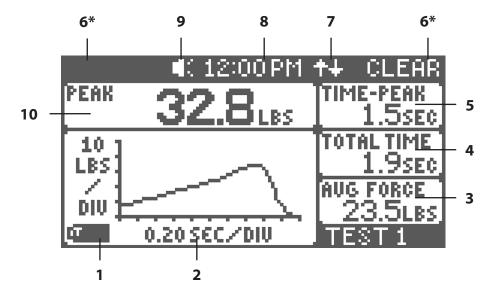
Test Screen

The Main Measurement Screen shows all measurement information that is being captured. This screen is shown whenever a measurement is in progress. (see diagram on next page)

- 1. Battery Indicator: Indicates the remaining capacity in the charge of the battery.
- 2. Force over Time Graph Area: The graph displays the data for the previously conducted test, and automatically populates the chart to maximize the viewing area. The Y-axis label shows the amount of force (in lbs, kg, or N), and the X-axis shows the time in seconds.
- 3. Avg Force: Average force exerted over the range.
- 4. Total Time: The total time is the total duration of the test in seconds.

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- 5. Time-Peak: Time to peak is the elapsed time in seconds from the start of the test until the maximum force has been reached.
 - Each of these three windows can have any of the following measurements displayed during or after a test is taken:
 - Real-Time Force: This displays the real time force that is measured during the test.
 - Time in Range: Cumulative time within the specified range
 - *Time* ↑ *Range*: Cumulative time above the specified range
 - Time ↓ Range: Cumulative time below the specified range
- 6. Top Button Function: This area shows the current function for the top button. In the Test screen window, shown above, the clear function clears the current test, and allows the user to take another test.
- 7. Wireless Communication Indicator: This character indicates when the wireless is enabled.
- 8. Time Display: This time is displayed and can be set manually or synced with a PC in the Options Menu.
- 9. Sound Indicator: Indicates whether beeper is on or off for the current test.
- 10. Peak Force: The peak force displays the maximum force during the test and displays what units the force is being measured in (lbs, kg, or N).

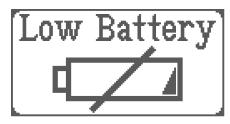


* Indicates elements that will move depending on chosen button orientation - set in OPTIONS menu

Low Battery Indicator Screen & Charging

The low battery indicator screen is shown when the battery needs to be charged. The screen will appear and then the system will power off. This screen will re-appear when the power button is pressed until the unit is recharged via the USB connector. The device should take about 45 minutes to charge 80% of the capacity, or about 2 hours for a full charge.





Test Setup Menu Screen

The Test Setup menu screen allows the user to setup various test options.

START

Starting a test can either be done by passing a FORCE THRESHOLD., or after a certain amount of TIME DELAY, triggered by the top button.

START FORCE/TIME DELAY

These options allow you to select customized force thresholds and time delays.



STOP THRESHOLD

If enabled, the test will end when the force applied drops below the value set in STOP FORCE. If disabled, the test will resume for the amount of time set by the TEST TIME.

STOP FORCE

If STOP THRESHOLD is enabled, each test will be stopped when the force is less than or equal to this force. Stop force cannot exceed start force.

AUTO CLEAR

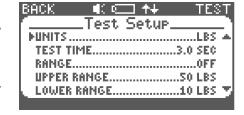
If enabled, manually clearing the data is not required prior to starting new tests.

UNITS

Allows selection of pounds (lbs), kilograms (kg), or Newtons (N).

TEST TIME

Allows users to select maximum time for testing.



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RANGE

Allows an upper and lower range to be enabled for testing. These ranges are set by setting the UPPER RANGE and LOWER RANGE.

RANGE TONES (↑ RANGE TONE, IN RANGE TONE, ↓ RANGE TONE)

Range tones are enabled by turning on each corresponding tone. The \uparrow RANGE TONE is a single beep. The IN RANGE TONE is two quick beeps. The \downarrow RANGE TONE is three quick beeps.



PEAK ONLY

Displays only the peak on the main screen, allowing for quick back-to-back testing. **Note: Data** is not saved in this mode. Once the screen is cleared or the next test begins, previous data will be lost.

ARROW FUNCTION

Sets the function of the arrow buttons on the Test Screen. SCROLL allows scrolling through the saved tests. GRAPH allows the graph enlargement.

Saved Data Menu Screen

The Saved Data menu screen allows users to manage tests that have been saved in the internal memory.







BACK

Options Menu Screen

The Options menu allows user to customize the setup of their unit.

WIRELESS

Toggles on/off the module for wireless connection.

BACK C T+ TEST Options WIRELESS OFF DISPLAY 1 TIME-PEAK DISPLAY 2 TOTAL TIME DISPLAY 3 AUE FORCE BUTTON ORIENTATION RIGHT

Options_

PC TIME SYNC.....ON

DATE......1/01/15 TIME......12:00 PM

DISPLAYS 1, 2, 3

Correspond to the customizable measurement areas on the Test Screen

BUTTON ORIENTATION

Switches the functionality of the top buttons, allowing for use in either hand.

BACKLIGHT

Toggles unit's backlight on/off.

SOUND

Toggles unit's sound on/off.

PC TIME SYNC

Allows the HHD to automatically set its time when connected to HHD Software.

DATE

Updates the HHD system date.

TIME

Updates the HHD system time.

Information Menu Screen

The Information menu screen provides a contact email and various information about the HHD.



Resets

To restore HHD to factory defaults, press MENU/SELECT and navigate to the Information screen. Press and hold MENU/SELECT then press the upper left button until screen reads "Restored Defaults".

Hard Reset: If the HHD freezes press MENU/SELECT and the upper right button until the unit powers off.

Firmware Updates

Lafayette Instrument periodically updates the firmware for select products. Visit lafayetteevaluation.com to download our Firmware Updater software. The Hand-held Dynamometer can be updated by plugging in the usb charger into your computer and downloading the current version of the firmware via the Firmware Updater.

Dynamometer Cleaning

Hard surfaces can be cleaned with a bleach-free sanitizing wipe. Alcohol wipes may also be used. Cloth or foam surfaces can be cleaned with anti-bacterial soap and water and allowed to air dry. Care must be taken to not allow water to penetrate the enclosure as damage to the circuit may occur. Disposable sanitary covers are available on the stirrup pad that comes into direct contact with the patient's skin. Do not reuse disposable covers.

Disclaimer: These cleaning instructions for Lafayette Instrument products are a recommendation of compatible cleaning materials only. Product end users are responsible for instituting an appropriate cleaning regimen utilizing best practices and techniques. Lafayette Instrument assumes no responsibility for the cleanliness or sanitation of the products after initial use nor makes any claim that the use of the recommended cleaning materials mitigates all risk of potential cross infection.

Appendix A - Torque measurements with the HHD

In some research and rehabilitation applications, it is necessary to obtain torque measurements for the limb being tested. Torque is often a more accurate indicator of total strength because it takes into account the length of the muscle being tested. The Lafayette Hand-held Dynamometer (HHD) can be used to obtain torque values through a series of basic calculations.

Torque is measured in units of Newton meters (Nwm) in the Metric system and in foot pounds (ftwlbs) in the English system. Torque is the product of the force applied times the distance between the force and the pivot point (usually a joint).

Equations for obtaining torque readings with the HHD using metric values:

Torque = Force * Distance

Where force equals the HHD reading converted to Newtons and distance is the length between where the force is applied and the joint being tested in meters.

Newtons conversions: 1 pound = 4.45 Newtons; 1 kilogram = 9.81 Newtons Newtons are calculated at sea level.

Normative Strength can also be quantified as torque per kilogram bodyweight (Nwm/kg). This value is obtained by dividing the torque by the person's bodyweight in kg.

FCC Compliance Statement

Contains FCC ID: T9J-RN42

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The FCC ID for the HHD is available via the device menu by selecting **MENU > INFORMATION**.

CE - Declaration of Conformity

World Headquarters

SRN:

EU Authorised Representative AJW Technology Consulting GmbH

Lafayette Instrument Company 3700 Sagamore Parkway North Lafayette, IN 47904 U.S.A.

Breite Straße 3 40213 Düsseldorf Germany

Pending

Product/Trade Name: Lafayette Hand-Held Dynamometer (HHD)

Model Designations: Lafayette Hand-Held Dynamometer 01165

Accessories: 01163CS HHD Curved Stirrup

> 01163LFS **HHD Large Flat Stirrup HHD Small Flat Stirrup** 01163SFS

Basic UDI: 0855170007STRENGTHTESTV9

RISK CLASS:

The above listed devices are hereby confirmed to conform to the essential requirements of the European Union Medical Device Regulations (EU 2017/745), Electromagnetic Compatibility Directive (2014/30/EU), and the Restriction of Hazardous Substances Directive (EU 2015/863)

For the evaluation regarding the electromagnetic compatibility requirements, the following standards were applied:

Electromagnetic Compatibility:

Electrical Safety: IEC 60601-1-1:2000

IEC 60601-1-2:2007-03

CISPR 11

IEC 61000-4-2

IEC 61000-4-3

IEC 61000-4-8

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Effective Date: October 19, 2021

Person responsible for making this declaration:

Name: Brent E. Smitley

Position/Title: Engineering Manager, Lafayette Instrument Company

Place: Lafayette, Indiana U.S.A.

Symbol Glossary

The following glossary describes the symbols included on the device label. Some symbols may not apply to this device.



Manufacturer

Indicates the medical device manufacturer ISO 15223-1:2016 Ref. 5.1.1



Authorized Representative

Indicates authorized representative in the EU ISO 15223-1:2016 Ref. 5.1.2



Date of Manufacture

Indicates date when device was manufactured ISO 15223-1:2016 Ref. 5.1.3



Use by Date

Indicates date after which the device is not to be used ISO 15223-1:2016 Ref. 5.1.4



Batch Code

Identifies the manufacturer's lot or batch ISO 15223-1:2016 Ref. 5.1.5



Catalog Number

Indicates the manufacturer's part ISO 15223-1:2016 Ref. 5.1.6



Serial Number

Identifies the manufacturer's serial number ISO 15223-1:2016 Ref. 5.1.7



Sterile

Indicates that a device has been subject to sterilization ISO 15223-1:2016 Ref. 5.2.1



Do not use if package is damaged

Indicates device should not be used if ISO 15223-1:2016 Ref. 5.2.8



Non-Sterile

Indicates a device has not been subject to sterilization

ISO 15223-1:2016 Ref. 5.2.7



Fragile, handle with care

Indicates device that needs careful handling ISO 15223-1:2016 Ref. 5.3.1



Keep away from sunlight

Indicates a device needs protection from sunlight

ISO 15223-1:2016 Ref. 5.3.2



Temperature limit

Indicates upper and lower temperature ISO 15223-1:2016 Ref. 5.3.7



Keep dry

Indicates device should be protected from moisture

ISO 15223-1:2016 Ref. 5.3.4



Do not reuse

Indicates a single use device ISO 15223-1:2016 Ref. 5.4.2



Consult Instructions for use

Prompts the user to consult the user manual

ISO 15223-1:2016 Ref. 5.4.3



Contains latex

Indicates the presence of natural rubber ISO 15223-1:2016 Ref. 5.4.5



Caution

Indicates the need to review cautionary information

ISO 15223-1:2016 Ref. 5.4.4



Humidity Limitation

Indicates the upper and lower limits of humidity ISO 15223-1:2016 Ref. 5.3.8



CE Mark

Product is certified for sale in the EU Regulation (EC) No. 765/2008 Annex II



Made in the USA

Device was manufactured in the USA No Standard Applicable



Medical Device

Enclosed equipment is classified as a medical device No Standard Applicable



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Terms and Conditions

LIC Worldwide Headquarters

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Larayette, IIV 47 700, 037

Lafayette Instrument Europe:

Phone: +44 1509 817700 Fax: +44 1509 817701

Email: eusales@lafayetteinstrument.com

Phone, Fax, Email or Mail-in Orders

All orders need to be accompanied by a hard copy of your purchase order. All orders must include the following information:

- Quantity
- Part Number
- Description
- Your purchase order number or method of pre-payment
- Your tax status (include tax-exempt numbers)
- Shipping address for this order
- · Billing address for the invoice we'll mail when this order is shipped
- Signature and typed name of person authorized to order these products
- Your telephone number
- Your email address
- Your FAX number

Domestic Terms

There is a \$50 minimum order. Open accounts can be extended to most recognized businesses. Net amount due 30 days from the date of shipment unless otherwise specified by us. Enclose payment with the order; charge with VISA, MasterCard, American Express, or pay COD. We must have a hard copy of your purchase order by mail, E-mail or fax. Students, individuals and private companies may call for a credit application.

International Payment Information

There is a \$50 minimum order. Payment must be made in advance by: draft drawn on a major US bank; wire transfers to our account; charge with VISA, MasterCard, American Express, or confirmed irrevocable letter of credit. Proforma invoices will be provided upon request.

Exports

If ordering instrumentation for use outside the USA, please specify the country of ultimate destination, as well as the power requirements (110V/60Hz or 220V/50Hz). Some model numbers for 220V/50Hz will have a "*C" suffix.

Quotations

Quotations are supplied upon request. Written quotations will include the price of goods, cost of shipping and handling, if requested, and estimated delivery time frame. Quotations are good for 30 days, unless otherwise noted. Following that time, prices are subject to change and will be re-quoted at your request.

Cancellations

Orders for custom products, custom assemblies or instruments built to customer specifications will be subject to a cancellation penalty of 100%. Payment for up to 100% of the invoice value of custom products may be required in advance. Cancellation for a standard Lafayette Instrument manufactured product once the product has been shipped will normally be assessed a charge of 25% of the invoice value, plus shipping charges. Resell items, like custom products, will be subject to a cancellation penalty of 100%.

Exchanges and Refunds

Please see the cancellation penalty as described above. No item may be returned without prior authorization of Lafayette Instrument Company and a completed Return Form. A copy of the Return Form or your assigned Return # (you will receive this via email after submitting the form) must be included with the returned goods. The merchandise should be packed well and fully insured. Unopened merchandise may be returned prepaid within thirty (30) days after receipt of the item and in the original shipping carton. Collect shipments will not be accepted. Returned products must be in saleable condition, and credit is subject to inspection of the merchandise.

Repairs

Instrumentation may not be returned without prior authorization by Lafayette Instrument Company and a completed Return Form. When you complete the

Form, or call Lafayette Instrument, you will receive a Return #. Your Return # number will be good for 30 days. Address the shipment to:

Lafayette Instrument Company 3700 Sagamore Parkway North Lafayette, IN 47904, USA.

Shipments cannot be received at the LIC PO Box. Items should be packed well, insured for full value, and returned along with a copy of the Return Form or the Return #. An estimate of repair will be given prior to completion OnLY if requested in an enclosed cover letter. We must have a completed purchase order by mail or fax, or repair work cannot commence for non-warranty repairs.

Damaged Goods

Damaged instrumentation should not be returned to Lafayette Instrument prior to a thorough inspection. If a shipment arrives damaged, note damage on delivery bill and have the driver sign it to acknowledge the damage. Contact the delivery service, and they will file an insurance claim. If damage is not detected at the time of delivery, contact the carrier/shipper and request an inspection within 10 days of the original delivery. Please call the Lafayette Instrument Customer Service Department for repair or replacement of the damaged merchandise.

Limited Warranty

Lafayette Instrument Company warrants equipment manufactured by the company to be free of defects in material and workmanship for a period of one year from the date of shipment, except as provided hereinafter. The original manufacturer's warranty will be honored by Lafayette Instrument for items not manufactured by Lafayette Instrument Company, i.e. resell items. This assumes normal usage under commonly accepted operating parameters and excludes consumable products.

Warranty period for repairs or used instrumentation purchased from Lafayette Instrument is 90 days. Lafayette Instrument Company agrees either to repair or replace, at its sole option and free of part charges to the customer, instrumentation which, under proper and normal conditions of use, proves to be defective within the warranty period. Warranty for any parts of such repaired or replaced instrumentation shall be covered under the same limited warranty and shall have a warranty period of 90 days from the date of shipment or the remainder of the original warranty period whichever is greater. This warranty and remedy are given expressly and in lieu of all other warranties, expressed or implied, of merchantability or fitness for a particular purpose and constitutes the only warranty made by Lafayette Instrument Company.

Lafayette Instrument Company neither assumes nor authorizes any person to use of its instrumentation. Lafayette Instrument Company shall have no liability whatsoever for special, consequential, or punitive damages of any kind from any cause arising out of the sale, installation, service or use of its instrumentation. All products manufactured by Lafayette Instrument Company are tested and inspected prior to shipment. Upon prompt notification by the Customer, Lafayette Instrument Company will correct any defect in warranted equipment of its manufacture either, at its option, by return of the item to the factory, or shipment of a repaired or replacement part. Lafayette Instrument Company will not be obliged, however, to replace or repair any piece of equipment, which has been abused, improperly installed, altered, damaged, or repaired by others. Defects in equipment do not include decomposition, wear, or damage by chemical action or corrosion, or damage incurred during shipment.

Limited Obligations Covered by this Warranty

- In the case of instruments not of Lafayette Instrument Company manufacture, the original manufacturer's warranty applies.
- Shipping charges under warranty are covered only in one direction. The customer is responsible for shipping charges to the factory if return of the part is required.
- This warranty does not cover damage to components due to improper installation by the customer.
- Consumable and or expendable items, including but not limited to electrodes, lights, batteries, fuses, O-rings, gaskets, and tubing, are excluded from warranty.
- Failure by the customer to perform normal and reasonable maintenance on instruments will void warranty claims.
- 6. If the original invoice for the instrument is issued to a company that is not the company of the end user, and not an authorized Lafayette Instrument Company distributor, then all requests for warranty must be processed through the company that sold the product to the end user, and not directly to Lafayette Instrument Company.

Export License

The U.S. Department of Commerce requires an export license for any polygraph system shipment with an ULTIMATE destination other than: Australia, Japan, New Zealand or any NATO Member Countries. It is against U.S. law to ship a Polygraph system to any other country without an export license. If the ultimate destination is not one of the above listed countries, contact us for the required license application forms.