

Lafayette Professional Hand Dynamometer

User Instructions



3700 Sagamore Parkway North
Lafayette, IN 47904 USA
Tel: (765) 423-1505

info@lafayetteinstrument.com
www.lafayetteinstrument.com

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Description

The Lafayette Professional Hand Dynamometer (PHD) offers many features for both routine screening work and for evaluating hand trauma and disease.

Dual-Scale Readout

Our Dynamometer displays grip force in pounds (200 lbs max) and kilograms (90 kg max).

Peak-Hold Needle

For convenience and easy recording, the Lafayette PHD automatically retains the highest reading. This reading remains on the gauge until the examiner resets it.

Accurate and Reproducible

Isometric in use, with almost no perceptible motion of the handles, regardless of grip strength. The hand grasp is both comfortable and effective. These features combine to ensure accurate, reproducible results.

Adjustable Handle

To accommodate various size hands, the Lafayette PHD handle adjusts to five grip positions: from 1 3/8 to 3 3/8 inches, in half-inch increments.

Benefits

Detection of the Malingerer. For various reasons, some patients will be reluctant to exert maximum effort in grip force evaluation. Repeated tests after short rest periods will detect the malingering patient. To determine whether the patient is exerting maximum effort:

- a. Test grip in the usual manner, taking readings with the hand grip in all positions on the dynamometer.
- b. Test the normal hand, followed by the injured hand, allowing the subject to see readings.
- c. After about five minutes, repeat the test.

Usually, if the subject has carried out the test will full effort, there will be less than 10% variation in results for various grip positions. But if he has exerted less-than-full-effort, there will be a larger, erratic variation, sometimes as much as 100% between the two tests.

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Operation

When you use the Lafayette PHD, please remember that it is a precision instrument and its accuracy can be impaired by abuse. Have the subject use the wrist safety strap to minimize the chance of dropping the dynamometer.

To use the dynamometer

1. Set the adjustable handle to the desired spacing. If the handle is not replaced in the correct position, the readings will not be accurate.
2. Rotate the red peak-hold needle counterclockwise to 0.
3. Let the subject arrange the instrument so that it fits in his hand comfortably. Ask him to squeeze with his maximum strength. The peak-hold needle will automatically record the highest force he has exerted.
4. After the subject has used the instrument, record the reading.
5. Reset the peak-hold needle to zero before recording new readings.



Suggested Standard Procedures

1. Sit or stand comfortable
2. Shoulder adducted and neutrally rotated
3. Elbow flexed to 90 degrees
4. Forearm in neutral position
5. Wrist in neutral position
6. Each test should be repeated 3 times
7. Use the average as the recorded result

Suggested Interfering Factors

The following factors have shown positive correlation with grip strength:

1. Weight
2. Hand width
3. Height
4. Mesomorphy

Service Tips

The Lafayette PHD is designed to provide reliable service, with minimum maintenance, over a period of many years. To make sure the instrument is reading accurately, it's a good idea to make a few checks, occasionally, as listed below.

Wrist Strap

The Lafayette PHD is equipped with a wrist strap. Simply place your hand through the strap before grasping the body of the dynamometer to protect the instrument from damage if dropped.

Calibration

The instrument is calibrated at the factory using a custom calibration device. To ensure proper operation, the instrument should be returned to the manufacturer for calibration on a regular, preferably, annual basis. If the instrument has been dropped or there is some particular reason to suspect that the calibration is in error, the instrument should be serviced by the manufacturer immediately.

Zero Reading

The gauge needle may be above or below the zero reading upon receipt of the instrument. The gauge on this instrument is sensitive to pressure changes due to changes in altitude and will most likely require an adjustment to re-zero the instrument. Follow these steps to return the gauge needle to zero:

1. Unscrew (counter clockwise) and remove the lens from the gauge (the red peak-hold needle is attached to the lens)
2. Remove the handle (to prevent applying pressure during this process)
3. Place the instrument on a sturdy surface
4. Using a small slotted screwdriver, rotate the slotted screw counter clockwise in the gauge dial face until the needle is below zero (if it is already zero, turn the cam until it is slightly farther below zero)
5. Turn the screw in the reverse direction until the gauge needle is almost touching the zero line
6. Reattach the gauge lens and the handle
7. Pick up and squeeze to apply pressure to the instrument a few times
8. Place the instrument back on a sturdy surface and return the red peak-hold needle to zero by turning the center knob
9. Check to see that the red peak-hold needle is at zero
10. If the red peak-hold needle is not on zero, repeat steps 1-10 until the red peak-hold needle is at zero



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Red Peak-Hold Needle

Check for excessive friction in the red peak-hold assembly by turning the peak-hold knob in the lens counterclockwise. If the peak-hold needle deflects the gauge needle, return the instrument for service. Likewise, if the red peak-hold needle moves too freely, (i.e. spins without pressure applied) return the instrument for service.

Cleaning

Cleaning with mild antibacterial soap and water is recommended. Do not soak or saturate the device with water. Handle and posts can be cleaned with an isopropyl alcohol wipe. Do not use alcohol on the plastic gauge faceplate or cover.

Disclaimer: The 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.

Hydraulics

Any sign of hydraulic oil is an indication of damage to the instrument which requires service by the manufacturer.

Hydraulic Fluid

Lafayette hand and pinch dynamometers are filled with a biodegradable, plant based hydraulic fluid. Under normal circumstances, the fluid is contained within the device and does not come into contact with the user or patient. If the device is damaged, the fluid can leak out and human exposure to the fluid is a possibility. The fluid is non-toxic and contains no chemicals known to cause cancer, birth defects or other reproductive harm. Despite the relative safety of the fluid, precautions should be taken to limit exposure. If exposure occurs, the following guidelines from the Material Safety Data Sheet (MSDS) of the fluid should be followed.

- **ORAL:** DO NOT INDUCE VOMITING. If conscious, give 2 glasses of water. Get immediate medical attention.
- **EYE:** Flush with water at least 15 minutes. Get medical attention if eye irritation develops or persists.
- **SKIN:** Wash with soap and water. Remove contaminated clothing. Get medical attention if irritation develops. Launder contaminated clothing before reuse.
- **INHALATION:** Remove exposed person to fresh air if adverse effects are observed. If breathing is labored, administer oxygen. If breathing has stopped, apply artificial respiration. If irritation persists, get medical attention.



Table: Average Grip-Strength vs Age

| Age | Hand | Males | | Females | |
|--------|------|-------|------|---------|------|
| | | Mean | SD | Mean | SD |
| 6-7 | R | 32.5 | 4.8 | 28.6 | 4.4 |
| | L | 30.7 | 5.4 | 27.1 | 4.4 |
| 8-9 | R | 41.9 | 7.4 | 35.3 | 8.3 |
| | L | 39.0 | 9.3 | 33.0 | 6.9 |
| 10-11 | R | 53.9 | 9.7 | 49.7 | 8.1 |
| | L | 48.4 | 10.8 | 45.2 | 6.8 |
| 12-13 | R | 58.7 | 15.5 | 56.8 | 10.6 |
| | L | 55.4 | 16.9 | 50.9 | 11.9 |
| 14-15* | R | 77.3 | 15.4 | 58.1 | 12.3 |
| | L | 64.4 | 14.9 | 49.3 | 11.9 |
| 16-17* | R | 94.0 | 19.4 | 67.3 | 16.5 |
| | L | 78.5 | 19.1 | 56.9 | 14.0 |
| 18-19* | R | 108.0 | 24.6 | 71.6 | 12.3 |
| | L | 93.0 | 27.8 | 61.7 | 12.5 |
| 20-24 | R | 121.0 | 20.6 | 70.4 | 14.5 |
| | L | 104.5 | 21.8 | 61.0 | 13.1 |
| 25-29 | R | 120.8 | 23.0 | 74.5 | 13.9 |
| | L | 110.5 | 16.2 | 63.5 | 12.2 |
| 30-34 | R | 121.8 | 22.4 | 78.7 | 19.2 |
| | L | 110.4 | 21.7 | 68.0 | 17.7 |
| 35-39 | R | 119.7 | 24.0 | 74.1 | 10.8 |
| | L | 112.9 | 21.7 | 66.3 | 11.7 |
| 40-44 | R | 116.8 | 20.7 | 70.4 | 13.5 |
| | L | 112.8 | 18.7 | 62.3 | 13.8 |
| 45-49 | R | 109.9 | 23.0 | 62.2 | 15.1 |
| | L | 100.8 | 22.8 | 56.0 | 12.7 |
| 50-54 | R | 113.6 | 18.1 | 65.8 | 11.6 |
| | L | 101.9 | 17.0 | 57.3 | 10.7 |
| 55-59 | R | 101.1 | 26.7 | 57.3 | 12.5 |
| | L | 83.2 | 23.4 | 47.3 | 11.9 |
| 60-64 | R | 89.7 | 20.4 | 55.1 | 10.1 |
| | L | 76.8 | 20.3 | 45.7 | 10.1 |
| 65-69 | R | 91.1 | 20.6 | 49.6 | 9.7 |
| | L | 76.8 | 19.8 | 41.0 | 8.2 |
| 70-74 | R | 75.3 | 21.5 | 49.6 | 11.7 |
| | L | 64.8 | 18.1 | 41.5 | 10.2 |
| 75+ | R | 65.7 | 21.0 | 42.6 | 11.0 |
| | L | 55.0 | 17.0 | 37.6 | 8.9 |

* The mean scores for individuals, aged 14-19 years, may be slightly low (0-10 lb lower than they should be) due to instrument error detected after the study.

References

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Warranty

The Lafayette PHD has a 1 year parts and labor warranty. Please contact our service department at service@lafayetteinstrument.com to schedule your yearly calibration or repair. Any attempt to service or calibrate the dynamometer outside of Lafayette Instrument will void the warranty.

CE - Declaration of Conformity

World Headquarters

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

EU Authorised Representative

AJW Technology Consulting GmbH
Breite Straße 3
40213 Düsseldorf
Germany

SRN: Pending

Product/Trade Name: Hand and Pinch Dynamometers

| | | |
|----------------------------|--------|---|
| Model Designations: | 5030L1 | Lafayette Professional Hand Dynamometer |
| | 5030P1 | Lafayette Hydraulic Pinch Gauge |
| | 5030K1 | Professional Hand Evaluation Kit |
| | J00105 | Lafayette Hydraulic Grip Dynamometer |
| | J00109 | Hand Evaluation Kit |

Basic UDI: 0855170007STRENGTHTESTV9

RISK CLASS: 1

The above listed devices are hereby confirmed to conform to the essential requirements of the European Union Medical Device Regulations (EU 2017/745)

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. |

Legal Signature:



Symbol Glossary

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

| | | | |
|--|---|---|--|
|  | <p>Manufacturer Indicates the medical device manufacturer <i>ISO 15223-1:2016 Ref. 5.1.1</i></p> |  | <p>Authorized Representative Indicates authorized representative in the EU <i>ISO 15223-1:2016 Ref. 5.1.2</i></p> |
|  | <p>Date of Manufacture Indicates date when device was manufactured <i>ISO 15223-1:2016 Ref. 5.1.3</i></p> |  | <p>Use by Date Indicates date after which the device is not to be used <i>ISO 15223-1:2016 Ref. 5.1.4</i></p> |
|  | <p>Batch Code Identifies the manufacturer's lot or batch code <i>ISO 15223-1:2016 Ref. 5.1.5</i></p> |  | <p>Catalog Number Indicates the manufacturer's part number <i>ISO 15223-1:2016 Ref. 5.1.6</i></p> |
|  | <p>Serial Number Identifies the manufacturer's serial number <i>ISO 15223-1:2016 Ref. 5.1.7</i></p> |  | <p>Sterile Indicates that a device has been subject to sterilization <i>ISO 15223-1:2016 Ref. 5.2.1</i></p> |
|  | <p>Do not use if package is damaged Indicates device should not be used if opened <i>ISO 15223-1:2016 Ref. 5.2.8</i></p> |  | <p>Non-Sterile Indicates a device has not been subject to sterilization <i>ISO 15223-1:2016 Ref. 5.2.7</i></p> |
|  | <p>Fragile, handle with care Indicates device that needs careful handling <i>ISO 15223-1:2016 Ref. 5.3.1</i></p> |  | <p>Keep away from sunlight Indicates a device needs protection from sunlight <i>ISO 15223-1:2016 Ref. 5.3.2</i></p> |
|  | <p>Temperature limit Indicates upper and lower temperature limits <i>ISO 15223-1:2016 Ref. 5.3.7</i></p> |  | <p>Keep dry Indicates device should be protected from moisture <i>ISO 15223-1:2016 Ref. 5.3.4</i></p> |
|  | <p>Do not reuse Indicates a single use device <i>ISO 15223-1:2016 Ref. 5.4.2</i></p> |  | <p>Consult Instructions for use Prompts the user to consult the user manual <i>ISO 15223-1:2016 Ref. 5.4.3</i></p> |
|  | <p>Contains latex Indicates the presence of natural rubber latex <i>ISO 15223-1:2016 Ref. 5.4.5</i></p> |  | <p>Caution Indicates the need to review cautionary information <i>ISO 15223-1:2016 Ref. 5.4.4</i></p> |
|  | <p>Humidity Limitation Indicates the upper and lower limits of humidity <i>ISO 15223-1:2016 Ref. 5.3.8</i></p> |  | <p>CE Mark Product is certified for sale in the EU <i>Regulation (EC) No. 765/2008 Annex II</i></p> |
|  | <p>Made in the USA Device was manufactured in the USA <i>No Standard Applicable</i></p> |  | <p>Medical Device Enclosed equipment is classified as a medical device <i>No Standard Applicable</i></p> |

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Terms and Conditions

LIC Worldwide Headquarters

Toll-Free: (800) 428-7545 (USA only)

Phone: (765) 423-1505

Fax: (765) 423-4111

sales@lafayetteinstrument.com

export@lafayetteinstrument.com (Outside the USA)

Mailing Address:

Lafayette Instrument Company

PO Box 5729

Lafayette, IN 47903, USA

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 Return Goods Authorization (RGA#) number which must be affixed to the shipping label of the returned goods. The merchandise should be packed well, insured for the full value and returned along with a cover letter explaining the reason for return. 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. Product must be returned in saleable condition, and credit is subject to inspection of the merchandise.

Repairs

Instrumentation may not be returned without first receiving a Return Goods Authorization Number (RGA). When returning instrumentation for service, please call Lafayette Instrument to receive a RGA number. Your RGA 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 PO Box. The items should be packed well, insured for full value, and returned along with a cover letter explaining the malfunction. An estimate of repair will be given prior to completion ONLY if requested in your enclosed cover letter. We must have a hard copy of your 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 assume for it any other liability in connection with the sale, installation, service or 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

1. In the case of instruments not of Lafayette Instrument Company manufacture, the original manufacturer's warranty applies.
2. 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.
3. This warranty does not cover damage to components due to improper installation by the customer.
4. Consumable and/or expendable items, including but not limited to electrodes, lights, batteries, fuses, O-rings, gaskets, and tubing, are excluded from warranty.
5. 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.