SPLAYOMETER

Quantitative Diagnosis and Assessment

User Manual

Version 3

The Splayometer is a medical device intended for use by licensed healthcare professionals.
This manual is for informational purposes only.

Patent pending.

1. Overview

The Splayometer is a custom-designed digital force measurement device built for clinical use. It measures compressive or tensile force and displays readings on a built-in OLED screen. The device supports multiple measurement modes, unit switching, and a three-trial averaging protocol consistent with standard clinical dynamometry practices.

The device is operated using three buttons: ZERO, MODE, and CAL. All settings and calibration data are stored in memory and survive power cycles, including complete battery discharge.

1.1 Buttons

Button	Short Press	Long Press (2+ seconds)
ZERO	Zero the scale (all modes)	Show settings screen (calibration info, startup mode, display precision)
MODE	Cycle measurement mode (Live → Max Hold → Average)	Toggle display unit (kg ↔ lb)
CAL	Advance Average mode (start / save / reset)	Enter calibration mode

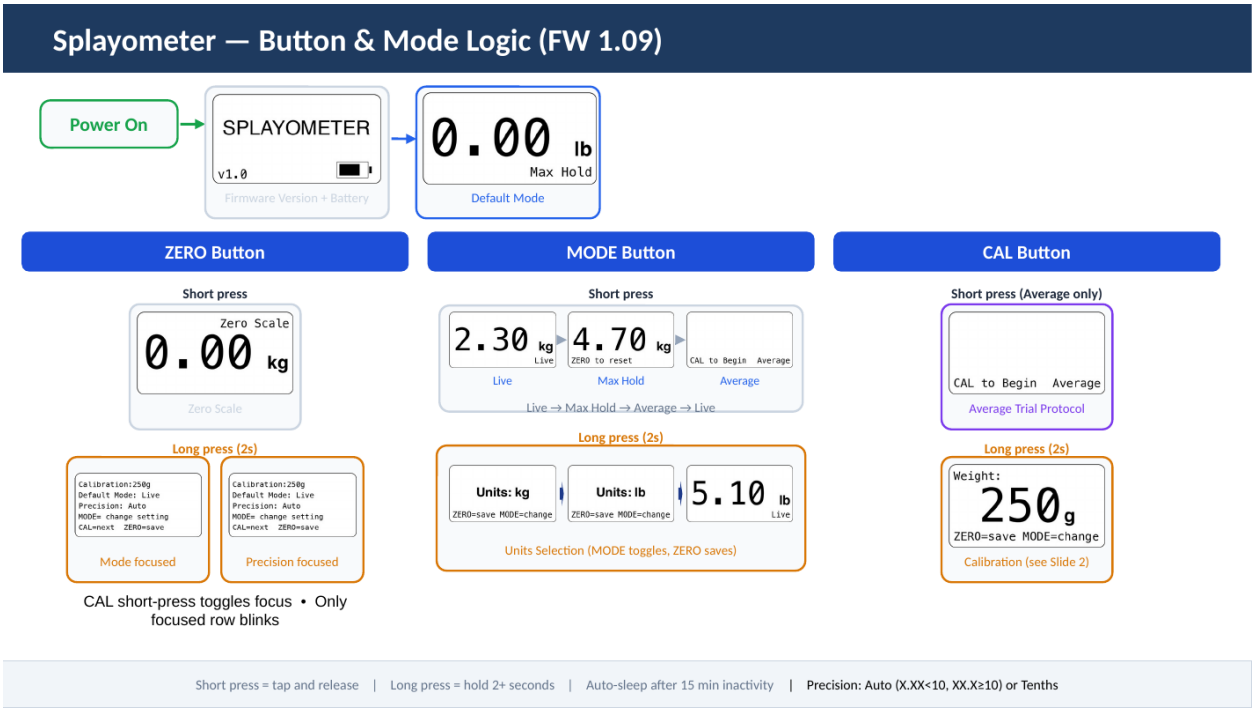
2. Warnings & Cautions

Read this section before using the Splayometer.

1. Do not exceed the rated capacity of the load cell. Exceeding the maximum load may permanently damage the sensor.
2. Do not immerse, submerge, or expose the device to running water.
3. Inspect the device, cable, and accessories for damage before each use. Do not use if damage is present.
4. Do not open, modify, or attempt to repair the device. The case is not user-serviceable. Doing so voids the warranty and may damage the device.
5. Charge only with a USB-C cable connected to a 5 V USB power source rated up to 1 A. Voltages above 5 V may damage the device.
6. Internal rechargeable lithium-ion battery. Do not puncture, crush, expose to fire, or heat above 140 °F (60 °C). The battery is not user-replaceable — return the device to the manufacturer for service.

3. Getting Started

Flip the power switch from O to I. The display will show a startup splash screen reading **"Splayometer"** with a battery level icon at the bottom of the screen, then switch to the default measurement mode.



4. Functions and Settings

4.1 Zero Scale

In any measurement mode, a short-press of the ZERO button sets the scale to 0.00, regardless of how much force is currently on the sensor.

4.2 Overload Indicator

If the measured force exceeds the rated capacity of the load cell, the display shows "---" instead of a number. Remove the load immediately to avoid damage.

4.3 Settings Screen

Press and hold **ZERO** for 2 or more seconds to display the settings screen. This screen shows three lines of information:

- **Calibration status:** the calibration weight used (e.g. "Cal: 500g") or "Cal: NONE" if uncalibrated.
- **Default startup mode:** the mode the device enters on power-up (Live, Max Hold, or Average). This value blinks to indicate it can be changed. Press **MODE** to cycle through the options. The new setting is saved and takes effect immediately.
- **Display Precision:** choose **Tenths** for tenths 0.0 or **Auto** for hundredths 0.00 precision (below a reading of 10 lb/kg).

To adjust settings:

1. Press **CAL** to switch between the Mode and Precision rows

2. Press **MODE** to cycle the focused setting options.
3. Press **ZERO** to exit settings.

4.4 Auto-Sleep

The display automatically turns off after 15 minutes of inactivity. Press any button to wake.

5. Measurement Modes

Press MODE briefly to cycle through the three measurement modes.

5.1 Live Mode

Displays the live force reading in real time; returns to 0 if load is removed.

To zero the scale before a measurement, press ZERO.

5.2 Max Hold Mode

Captures and holds the highest force reading since the last zero.

5.2.1 Standard Max Hold procedure:

7. Press MODE to select MAX HOLD mode. "Max Hold" appears in the bottom-right corner while the display is at zero. Once a force is applied the "Max Hold" label hides and "ZERO to reset" appears on the bottom-left; press ZERO to reset and the "Max Hold" label reappears.
8. Press ZERO to zero the scale. "Zero Scale" appears briefly in the top-right.
9. Instruct the patient to apply force (pinch or splay). The display tracks and holds the peak.
10. After the patient relaxes, read and record the held peak value.
11. Press ZERO to reset and prepare for the next measurement.

5.3 Average Mode: 3-Trial Protocol (See flow chart on next page)

This mode follows the standard clinical dynamometry protocol of three sequential maximum-effort trials with the average and standard deviation reported.

5.3.1 3-Trial procedure:

1. Press MODE to select AVERAGE mode. The display has no value yet — the bottom row reads "CAL to Begin" on the left and "Average" on the right.
2. **Press CAL.** The bottom row shows "CAL to save Trial#1" — Trial 1 is active.
3. Patient applies maximum force. The display tracks the running peak.
4. **Press CAL** to save Trial 1 and advance to Trial#2.
5. Repeat for Trial#2 and Trial#3, pressing CAL to save each.
6. After Trial 3 is saved, the display rotates every 2 seconds through three phases: the Average value (with "Average" in the bottom row), the Standard Deviation value (with "Standard Deviation" in the bottom row), and a blank display (with "CAL to Start Over" in the bottom row).

7. Record the values. Press CAL during the "CAL to Start Over" phase to begin a new 3-trial measurement.

Note: *ZERO is available at any time during the 3-Trial process to re-zero the scale. Press ZERO between trials if needed — the scale does not auto-zero between trials.*

4.3.2 Standard Deviation Calculation

Sample standard deviation (s) is calculated using:

$$s = \sqrt{\frac{(x_1 - \bar{x})^2 + (x_2 - \bar{x})^2 + (x_3 - \bar{x})^2}{2}}$$

Where:

- x_i = each trial value (x_1, x_2, x_3) — the three captured peaks
- $\bar{x}$ (x-bar) = mean of the trials = (x_1 + x_2 + x_3) / 3
- n = number of trials = 3
- $n - 1 = 2$ (the Bessel correction)

6. Units

The scale supports two display units: kilograms (kg) and pounds (lb). The selected unit is saved automatically and will be remembered after power-off.

To switch units:

1. Press and hold MODE for 2 or more seconds.
2. Press MODE to switch Units
3. Press ZERO to save change

Note: *Unit switching is available in all measurement modes. Units can be changed at any time without affecting the current measurement.*

7. Calibration

The Splayometer was calibrated in the factory using a 500g mass. The device includes a configurable calibration selection with presets of 100 g, 200 g, 500 g, 1000 g, and 2000 g.

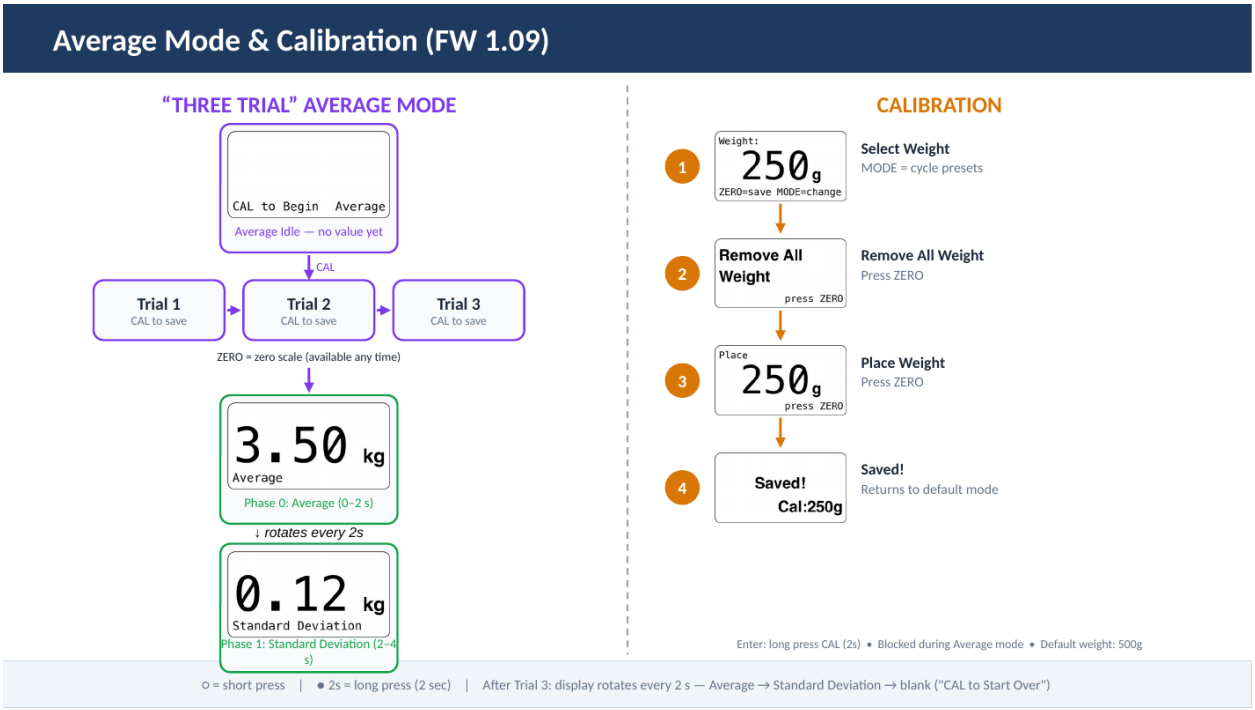
Calibration is retained even when the unit is turned off or the battery loses all charge.

7.1 Calibration Procedure (See flow chart below)

1. Remove all weight from the scale.
2. Press and hold **CAL** for 2 or more seconds to enter calibration mode.
3. The display shows "Weight:" with the currently selected weight (blinking). Press **MODE** to cycle through the preset weights (100, 200, 500, 1000, 2000 g). Press **ZERO** to confirm your selection.
4. The display prompts "Remove All Weight" with "press ZERO" at the bottom. Confirm the scale is unloaded, then press ZERO. The scale records the zero offset.

5. The display prompts "Place" with the selected weight (e.g. "500g") and "press ZERO" at the bottom. Place your calibration weight on the scale and press **ZERO**. The scale averages 10 readings and calculates the calibration factor.
6. The display briefly shows "Saved!" with the calibration weight confirmed (e.g. "Cal:500g"). The scale returns to the default measurement mode.

Note: *Calibration accuracy depends on the precision of the reference weight. Use a certified calibration weight for best results. A 500 g calibration weight is included with the Splayometer.*



8. USB Charging Port

If you purchased the Clinical Kit, a charger and cable were included. These are also available separately on shop.splayometer.com. You can connect any USB-C cable to the charging port and a 5V USB power source (computer, phone charger, USB hub). NOTE: Using a charging device with a voltage above 5V may damage the splayometer.

- When charging, a red light will appear near the charging port.
- When charged, the light will turn blue.

9. Cleaning & Maintenance

Wipe the enclosure with a soft cloth lightly dampened with isopropyl alcohol (up to 70%) or a hospital-grade disinfectant wipe. Do not immerse. Do not autoclave. Disconnect the USB charging cable before cleaning. The device contains no user-serviceable parts; if service is required, contact support@splayometer.com.

10. Support

Please go to splayometer.com to submit a support request, or email support@splayometer.com.

11. Troubleshooting

Symptom	Possible Cause	Solution
Measured value seems incorrect	Scale not calibrated	Perform the calibration procedure.
Reading drifts when nothing is on scale	Large Temperature change or vibration	Allow device to stabilize, then press ZERO to re-zero.
Display shows "---"	Load exceeds max capacity	Remove load. Do not exceed rated capacity.
Calibration shows "---" after placing weight	Weight exceeds max capacity	Use a lighter calibration weight within the rated range.
Display is blank / off	Auto-sleep activated	Press any button to wake the display. The device sleeps after 15 minutes of inactivity.

12. Device Identification & Regulatory Information

12.1 Manufacturer and Place of Business

Manufactured by Metric Devices.
Metric Devices
68 Harrison Ave Ste 605 #201230
Boston, MA 02111-1929 USA
splayometer.com

Country of origin: United States.

12.2 Device Classification and Intended Use

The Splayometer DS01 is a U.S. FDA Class I medical device: a digital dynamometer (force-measurement instrument) intended to measure compressive and tensile forces in clinical assessment, monitoring, and research applications. It is intended for use by licensed healthcare professionals.
For Professional Use Only. The Splayometer is not intended for use by patients, consumers, or other unlicensed persons.

12.3 Clinical Use Disclaimer

The Splayometer provides quantitative force-measurement data only. It does not diagnose, treat, or recommend treatment. Clinical interpretation and decision-making remain the sole responsibility of the licensed healthcare professional.

12.4 Contraindications

None known. Clinical judgment governs use in any specific assessment context.

12.5 Electrical and Charging Specifications

Internal rechargeable battery: 3.7 V, 1100 mAh (nominal). Charging input: USB-C, 5 V DC, 1 A. Use only a USB power source rated 5 V; voltages above 5 V may damage the device.

12.6 Operating & Storage Conditions

- Operating temperature: 50–104 °F (10–40 °C)
- Operating humidity: 30–85% RH, non-condensing
- Storage temperature: −4 to 140 °F (−20 to 60 °C)
- Operating altitude: up to 6,500 ft (2,000 m)
- Use indoors in a clean, dry clinical environment.

12.7 Disposal & Recycling

The Splayometer contains a rechargeable lithium-ion battery and electronic components. Do not dispose of in household trash. Return the device to Metric Devices for recycling, or take it to a certified electronics and battery recycling facility in accordance with local regulations.

12.8 Reporting Adverse Events

Report any serious adverse event involving the Splayometer to Metric Devices at support@splayometer.com and to the U.S. FDA at fda.gov/medwatch.

12.9 Instructions for Use (eIFU) Availability

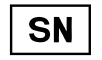
This document constitutes the Instructions for Use (IFU) for the Splayometer DS01. The current revision is published in electronic form at **splayometer.com/pages/manual.pdf**. A printed paper copy is available at no additional cost on request, normally within three (3) business days. To request a paper copy, email support@splayometer.com or write to Metric Devices at the address above.

12.10 Patent, Trademark, and Warranty

Splayometer™ is a trademark of Metric Devices. Patent pending. The Splayometer DS01 is covered by the Metric Devices Limited Warranty and Return Policy, which is provided separately and is also available on request.

12.11 Symbols Glossary

The Splayometer label uses the following internationally-recognized symbols. References are to ISO 15223-1 “Medical devices — Symbols to be used with information to be supplied by the manufacturer.”

Symbol	Meaning
	Manufacturer — name and address of the legal manufacturer (ISO 15223-1 5.1.1).
	Date of manufacture — year and month the device was manufactured (ISO 15223-1 5.1.3).
	Catalogue number — manufacturer’s product/model code (ISO 15223-1 5.1.6).
	Serial number — unique identifier for this individual unit (ISO 15223-1 5.1.7).
	Batch code — production batch (lot) the device belongs to (ISO 15223-1 5.1.5).
	Consult instructions for use — read this manual before operating the device (ISO 15223-1 5.4.3).
	Caution — refer to instructions for use for important safety information (ISO 15223-1 5.4.4 / ISO 7000 0434A).
UDI	Unique Device Identifier — FDA-required machine-readable identifier (21 CFR 830). The barcode and human-readable line encode the device’s GTIN, production date, batch, and serial.

12.12 Limitation of Liability

Except as expressly set forth in the Metric Devices Limited Warranty, the Splayometer is provided “as is” without warranty of any kind, express or implied, including but not limited to implied warranties of merchantability or fitness for a particular purpose.