












SAFETY + INTERNATIONAL SYMBOLS

The following symbols are associated with the Midmark Spirometer Calibration Syringe.

Symbol	Description
	Catalogue number
	Shipping direction (this way up)
	Consult instructions for use
RxOnly	Federal law (USA) restricts this device to sale by or on order of a physician
	Manufacturer
	Manufacture date
	Use-by date
	Keep away from sunlight
	Keep dry
	Temperature limits to which the medical device can be safely exposed
	Do not use if package is damaged
	Serial number
	Caution

Manufactured for:
Midmark Corporation
60 Vista Drive
Versailles, OH 45380 USA
1.844.856.1230, option 2
midmark.com



Hans Rudolph, Inc.
8325 Cole Parkway
Shawnee, KS 66227 USA

MIDMARK SPIROMETER CALIBRATION SYRINGE

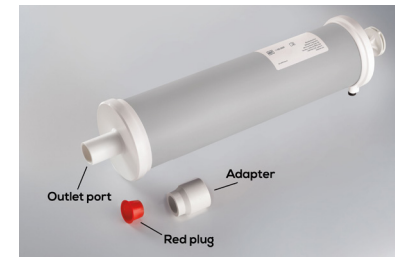
(P/N: 1-100-0009)

INSTRUCTIONS FOR USE

A. Intended Use

Volume calibration syringes are designed for testing and calibrating flow measurement devices. These calibration syringes are manually operated by actuating the plunger in and out of the cylinder. The outlet port of the syringe is attached to the device to be tested via the syringe adapter. When actuated, the calibration syringe displaces known volumes of air into the flow device. The operator then compares the calibration syringe volume with the flow measurement system to determine accuracy.

B. Connecting the Midmark Digital Spirometer to the Calibration Syringe



- Remove the red plug from the outlet port. Do not dispose of the plug as you can utilize it for the recommended leak test.
- Push the large end of the syringe adapter onto the syringe outlet port with enough pressure to ensure a secure, airtight seal.
- Attach a new Midmark disposable mouthpiece in the Midmark Digital Spirometer.
- Attach and press the disposable mouthpiece with the Spirometer into the small end of the adapter and ensure a secure, airtight seal.



Note: To avoid calibration errors, never attach the syringe directly to the disposable mouthpiece without the syringe adapter (P/N: 2-100-0043) that comes with the syringe. Placing the syringe outlet port inside the disposable mouthpiece will cause an inaccurate calibration and is not recommended. Also, check that there are no obstructions blocking the airflow of the disposable mouthpiece on either end.

C. Performing the Calibration Check

- Follow the instructions in the Midmark Digital Spirometer Operation Manual (56-78-0001) to perform the calibration check.

D. Normal Operation of the Midmark Spirometer Calibration Syringe

- Never push up or down on the plunger handle. Side pressure can cause a break in the air seal of the syringe.
- Push the plunger handle in by applying a smooth direct force to the center of the plunger handle.
- Always move the plunger handle fully from end to end when performing a calibration. You should feel the plunger firmly contact each end of the syringe. Avoid slamming or banging the plunger against the ends.
- Regularly inspect the syringe for damage. If the calibration syringe is dropped or visibly damaged, please contact Midmark for return and repair procedures.
- The calibration syringe should be stored and used in such a way as to maintain the same temperature and humidity of the testing site. This is best accomplished by keeping the calibration syringe in close proximity to the spirometer, but out of direct sunlight and away from heat sources.

E. Leak Test of the Midmark Spirometer Calibration Syringe

- With the plunger handle pulled all the way out, shut off air flow to the syringe by placing the palm of your hand tightly over the outlet port or by placing the supplied red plug in the outlet port.
- Attempt to push the plunger in while shutting off air flow. At the same time, place your ear close to the syringe end plate and listen for any hissing sounds, indicating a leak.
- If there is no movement of the plunger and no hissing sounds, there are no leaks in the syringe.
- If the syringe plunger is able to be pushed in or you hear hissing sounds, there likely is a leak in the syringe. Contact Midmark for return authorization and repair.

F. Cleaning + Maintenance

- Mild detergent (neutral pH 7), soap with tap water or standard hospital disinfectant/cleaners are recommended for periodic cleaning (wiping down) of the Midmark Spirometer Calibration Syringe.
- When using a detergent or soap solution, follow the manufacturer's instructions. Typical concentration of detergent is one ounce to 3.8 liters of water.
- With a clean, soft cloth dampened with the detergent solution, wipe down the outside surfaces of the syringe. Do not immerse the syringe in liquid.
- Use a dry soft cloth to remove any residue and dry the syringe.
- When using hospital disinfectant cleaners, follow the manufacturer's instructions. Dry thoroughly using a dry soft cloth before use.

Caution: ⚠ Do not use cleaning solutions or cloths inside the cylinder area of the syringe.

G. Recalibration

- Midmark recommends an annual recalibration of the calibration syringe. For information about receiving an annual recalibration, contact the Midmark Technical Service Team at 1.844.856.1230, option 2.

Warning

- Do not use ethylene oxide, steam sterilize or pasteurize the calibration syringe. This product cannot be sterilized.
- Do not disassemble this product. For service information, contact the Midmark Technical Service Team at 1.844.856.1230, option 2.
- Do not operate these syringes at temperatures above 25°C or below 15°C.
- It is the user's responsibility to validate any deviations from these recommended methods of processing.
- Federal law restricts this device to sale by or on the order of a physician.

Specifications

Total volume	3 Liter
Accuracy	+/- ½ of 1% full scale
Volume stroke	14 ¾" (37.47 cm)
Cylinder bore, ID	4" (10.16 cm)
Weight	5.3 lb (2,411 grams)

Recommendations

- The Midmark Digital Spirometer must be calibration checked using the supplied calibration syringe adapter.
- Midmark recommends leak testing of the calibration syringe daily before calibrating a spirometer.
- American Thoracic Society (ATS) and European Respiratory Society (ERS) recommend a daily calibration check of the spirometer before use.¹
- Use-by date: 2 years from manufacture date. Due to the lubricant inside the syringe, it is recommended that the syringe is used (stroked in primary application) before this date as best practice with lubricants in dynamic (reciprocating) applications.

Note: Please retain original packaging materials to expedite the return of your Midmark Spirometer Calibration Syringe for recalibration or service.

Source:

1 Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, Crapo R, Enright P, van der Grinten CP, Gustafsson P, Jensen R, Johnson DC, MacIntyre N, McKay R, Navajas D, Pedersen OF, Pellegrino R, Viegi G, Wanger J; ATS/ERS Task Force. Standardisation of spirometry. *European Respiratory Journal*. 2005 Aug;26(2):319-38. DOI:10.1183/09031936.05.00034805, PMID:16055882