Revision date: 2022-10-24

Medikro Calibration Syringe

User's Manual

for M9474

This 3L Calibration Syringe is part of the Medikro Spirometry System

Technical specifications	M9474 Calibration Syringe
Total volume	3000ml
Volume stroke	382 mm
Cylinder bore ID	100 mm
Outlet port adapters	Adapter with 29 mm internal diameter is made of thermoplastic elastomer (TPE).
Flow range	0…±15 l/s (user dependent, manually operated)
Temperature range	Operating: +10…+40°C / +50…+104°F Storage/Shipping: -20…+50°C / +14…+122°F
Relative humidity range	Operating: 15 … 90% RH Shipping/storage: 10 … 95%RH
Pressure range	Operating: 700 ... 1060 hPa Storage/Shipping: 500 ... 1060 hPa
Physical dimensions (LxWxH)	532 mm x 120 mm x 106 mm
Weight	1.9 kg

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Introduction

Medikro Calibration Syringes are used to check the calibration of Medikro spirometers. These syringes can also be used to check the volume accuracy of other volume or flow sensing spirometers.

Intended Use

The 3 Litres (Model M9474) Calibration Syringes are accessories which are used as a part of Medikro Spirometry System for spirometer calibration.

Incident Notification

Manufacturer and national competent authority must always be notified of a dangerous situation caused by a healthcare device or supply as soon as possible.

General Information

This 3L Calibration Syringe has been provided to you as part of the Medikro Spirometry System, and should be used in accordance with the User Manual provided with the Medikro Spirometry Software.

WARNING: No modification of this equipment is allowed.

CAUTION: To clean the Calibration Syringe, only wipe its external surfaces with damp cloth. All maintenance and internal cleaning of the Calibration Syringe is done by the Manufacturer.

Before start using the Calibration Syringe, it is recommended to perform at least 10 consecutive fill / empty cycles. This is made to ensure that the grease inside Calibration Syringe has spread evenly.

User Responsibility

This 3L Calibration Syringe is designed to perform in compliance with the description contained in this manual and the accompanying labels and inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided. The 3L Calibration Syringe should not be used if any of its parts are broken, worn, missing, incomplete, distorted, or contaminated. These parts should be replaced immediately.

Consult the User Manual associated with the Medikro Spirometry Software prior to using the 3L Calibration Syringe.

Repairs and Maintenance

All maintenance of products under warranty must be performed or accepted by the Manufacturer. Unauthorised maintenance will void the warranty. Calibration, service and repairs of Calibration Syringe is carried out only by the Manufacturer. There are no user serviceable components inside the equipment. If repairs or replacements are necessary, please contact Medikro.

RMA Policy and Procedure

Please inspect the shipped goods immediately upon receipt. If you find a problem with your order please contact Medikro immediately.

If a return cannot be avoided, the representative will record all necessary information and provide a Return Material Authorisation (RMA) number and return address. A Return Material Authorisation (RMA) number must be obtained before returning the product.

Calibration

Calibration is the procedure for establishing the relationship between sensor-determined values of flow or volume and the actual flow or volume. A calibration check is different from calibration and is the procedure used to validate that the device is within calibration limits, e.g.±3% of true. If a device fails its calibration check, then new calibration procedure or equipment maintenance is required.

Calibration forms an essential part of good laboratory practice. The spirometer should be calibrated daily as outlined in the ATS and ERS recommendations. Typically, the calibration is performed when the spirometer system is switched on. The calibration should be repeated when starting to use a new lot of flow transducers and also if there is a notable change during the day in environmental conditions (ambient temperature, pressure or humidity).

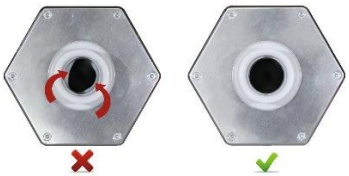
Maintenance Instructions

Inspection: Inspect the syringe for damage at all stages of handling. If damage is detected on any components of the syringe calibration, service and repairs is carried out only by the Manufacturer.

Leak Test: Leak test the Calibration Syringe by occluding the outlet port with one hand while pushing on the piston rod with the other. With your ear close to the piston rod end plate listen for a hissing sound indicating a leak. Air inside the syringe will compress but no hissing sound should be heard.

Rattle test: Rattle test the Calibration Syringe by holding the syringe with both hands and shaking the syringe vigorously. Sound of any loose parts or fittings is a clear sign of failure or breakage. Check if any foreign objects has been entered to the syringe and remove them through holes in front and back plates.

Adapter: Make sure (inspect visually) that the inner part of the adapter is settled evenly. If the inner part of the adapter is not settled evenly, press the adapter in place with your finger.



Sleeve Bearing: Check if Back Plate Sleeve Bearing is tightly fitted. Backlash in piston shaft direction is max. 0.1 mm. Larger movement or breakage in sleeve bearing itself require repair carried out only by the Manufacturer.

Cleaning & Storage Instructions

The syringes are supplied clean and nonsterile. Disinfection or sterilisation is not required because the syringe will not come into contact with patients.

Calibration syringe should be kept visually clean using clean soft cloths with water, clean soft cloths with mild detergent (neutral pH 7) or clean soft cloths with standard hospital disinfectant/cleaners. For wiping and drying use a clean dry cloth. Cleaning solutions or cloths should not be used inside the cylinder area of the syringe.

Cover the Calibration Syringe when not in use to avoid dust build-up and contamination.

EC DECLARATION OF CONFORMITY

Issued by
Medikro Oy,
Pioneerinkatu 3, 70800 Kuopio, Finland
FI-MF-000011841

Equipment Description:

This declaration of conformity is valid for the following product:

class I

(Spirometry/pulmonary function analyser syringe GMDN-code: 17250)

Device Group Basic UDI-DI: 6420099M9474LJ
M9474 Medikro Calibration Syringe, volume 3000 ml,
(GTIN: (01) 06420099000387)
Intended use: 3 liter (type M9474) calibration syringe for spirometer calibration and calibration checking.

CE Marking:

These products have been developed, produced and tested within quality management system according to ISO 13485:2016 and regulation (EU)2017/745.

The quality management system is ISO 13485:2016 certified by Eurofins Expert Services Ltd.

Applicable Directives:

The above products meet the essential requirements of the following directive(s):

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

Applied Standards:

Following standards are used to fulfil requirements:

- EN ISO 13485:2016
- EN ISO 14971:2019
- EN ISO 15223-1:2012
- EN ISO 20417:2021
- EN ISO 26782:2009
- EN 62366-1:2015/A1:2020

Place and Date
Kuopio, 2022-10-24

Tuukka Eloranta
Managing Director, Medikro Oy