

Made by: 29.10.2012 EL
 Checked by: 29.10.2012 MH
 Accepted by: 29.10.2012 MH

M8318
 1.0

SpiroSafe Flow Transducer Operating and Safety Instructions

Quality Control of Flow Transducers

Medikro M9256 SpiroSafe disposable flow transducers use the screen type pneumotach principle. Each SpiroSafe flow transducer is inspected and measured to ensure the quality.

Warnings

A warning statement in this installation guide identifies a condition or practice, which could lead to patient injury, illness, or death.

WARNING The disposable flow transducer is a Single-Use only product.

WARNING Do not wash the flow transducer. This increases the risk due to cross-contamination and changes the measuring results significantly. If disposable SpiroSafe flow transducer is washed, Medikro cannot guarantee the measuring accuracy of spirometry system.

WARNING The disposable flow transducers are packaged as non-sterile.

WARNING Do not mix the clean and used flow transducers together.

WARNING Use a new, clean disposable flow transducer for every patient.

Cautions

A caution statement in this installation guide identifies a condition or practice, which could lead to equipment failure, equipment damage, or data loss.

CAUTION Use this disposable flow transducer with the following spirometers: Medikro Domo, Medikro Nano, Medikro Primo, Medikro Pro and Medikro Evo.

CAUTION Cover the opened package.

CAUTION Calibrate the Spirometer daily according to the directions in the User Manual.

CAUTION Never calibrate the spirometer with a used flow transducer. This causes a risk of cross-contamination via the calibration syringe.

CAUTION The patient can easily hold the disposable flow transducer with his/her teeth (no hands required).

CAUTION Every time when a new package of SpiroSafe flow transducer is opened, check the calibration code from the label attached on the outer surface of the package. If the calibration code differs from the one currently in use, new code must be taken into use before resuming testing. Using wrong code may result in inaccurate results.

Before Using New Flow Transducer Package

When a new package of SpiroSafe flow transducers is taken into use, check the calibration code from the label attached on the outer surface of the package. If the calibration code differs from the calibration code currently in use, a new calibration code must be taken into use before resuming testing. Read the directions in the User Manual.



Calibration Code (for use with Medikro Spirometry Software only).

Disposal Instruction and materials

For EAN-codes: 6420099000554, 6420099000561, 6420099000578, 6420099000585, 6420099000592, 6420099000608 and 6420099000615

Materials: Flow Transducer: PEHD, Internal Bag: PELD, Single pack film: OPP and External Carton: Cardboard

Dispose of the flow transducer, the internal bag, and the external carton according to national or local laws or according to your facility's disposal policy. All materials are recyclable or burnable. The product safety sheet is available, upon request, for each of the materials.

The CE mark on this product indicates that it is in conformity with the provisions of Council Directive 93/42/EEC.

CAUTION Consult User Manual and other accompanying documents.

Medikro Oy

Mail address: P.O.Box 54, FI-70101 Kuopio, Finland
 Street address: Kellolahdentie 27, FI-70460 Kuopio, Finland

Tel: +358 17 283 3000
 Fax: +358 17 283 3300
 E-mail: sales@medikro.com
 Home page: www.medikro.com

Business Identity Code: 0288691-7
 V.A.T.: FI02886917
 Domicile: Kuopio