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SpiroSafe Flow Transducer Operating and Safety Instructions

Quality Control of Flow Transducers

SpiroSafe disposable flow transducers manufactured by Medikro use the screen type pneumotach principle. During production the flow transducers are subjected to continuous and detailed monitoring to ensure reliable quality and then given a lot number. The flow transducer performance relies on the flow characteristics of the pneumotach screen.

Each SpiroSafe flow transducer is inspected and measured. The basis of the measurement data assures the quality of the production lot.

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 the disposable SpiroSafe flow transducer is washed, Medikro cannot guarantee the measuring accuracy of the spirometry system.

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

WARNING Do not mix the clean and used flow transducers.

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 SpiroStar and SpiroMaster devices.

CAUTION Cover an opened flow transducer package.

CAUTION Calibrate the Spirometer according to the User's manual daily.

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

CAUTION Every time when a new package of SpiroSafe flow transducer is opened, check the production lot number from the label attached to the outer surface of the package. If this lot number differs from the lot number currently used, new linearisation file must be taken into use before resuming calibration or measurement. In this case follow the calibration instructions below. Using wrong linearisation file may result in inaccurate data.

Before Using New Flow Transducer Package

When new package of SpiroSafe flow transducer is taken into use, check the production lot number from the label attached to the outer surface of the package. If this lot number differs from the lot number currently used, new linearisation file must be taken into use before resuming testing.

SpiroSafe flow transducer package include a CD, which contains the linearisation file data. The included CD is for use with the Medikro Spirometry Software only.

Check the linearisation file of the SpiroSafe flow transducer and change it when needed in the Calibration window. Select the right linearisation file from the list box or select "New File" button. Follow the instructions given by the Medikro Spirometry Software. Or go to:

Device
Settings
Spirometry
Linearisation file

Select the right linearisation file from the list box. If the file is not listed, please select "New file" (at the top of the list) and follow the instructions given by the Medikro Spirometry Software.

Disposal Instructions

EAN- code: 6420099000011, 6420099000264

Materials: Flow Transducer: HDPE

Internal Bag: PP

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.