



Operating Manual

Spirometry

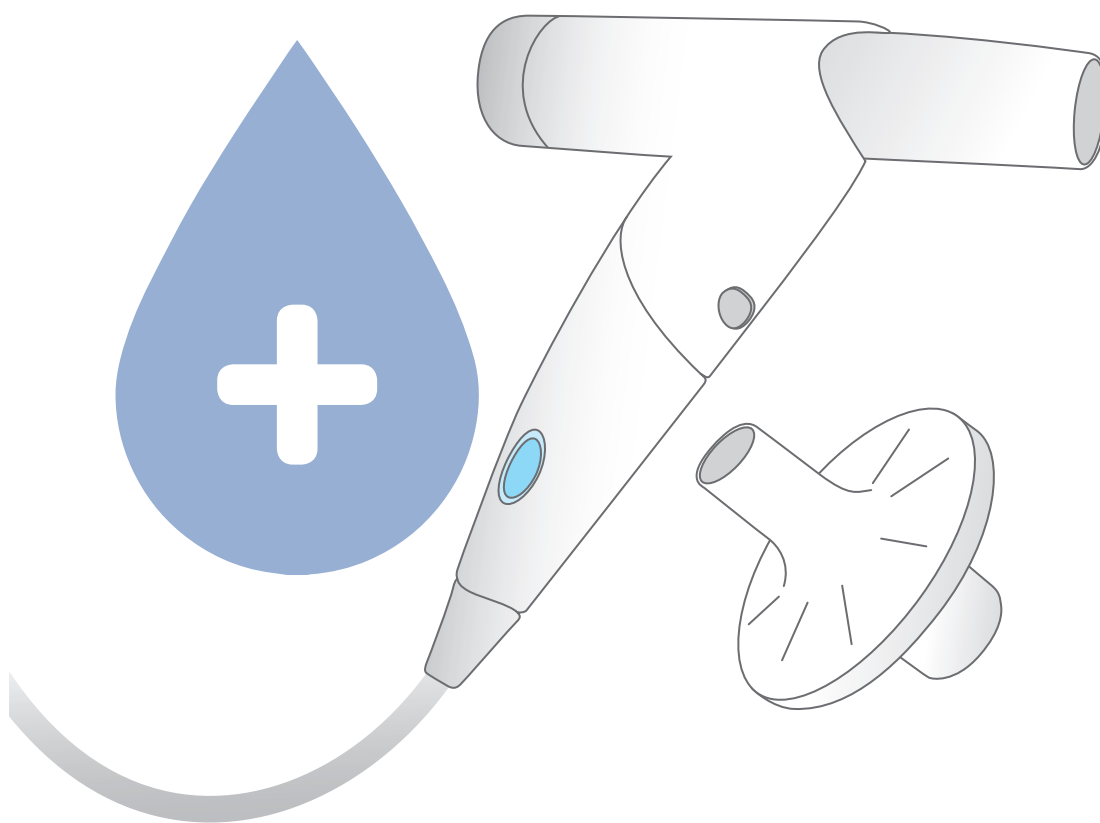
1 Safety

2 Hardware

3 Software

4 Hygiene

Part 4: Hygiene and disinfection for custo spiro mobile



Operating characteristics:

for custo spiro mobile
with custo diagnostic

MHY 0007 – DK 1708
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CE 0123

 **custo-med**
EXCELLENCE IN DIAGNOSTICS



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The manufacturer reserves the right to change the information in this Operating Manual without prior notice. The current version can be downloaded from our website: www.customed.de.

CAUTION:

This Operating Manual is part of a modular system consisting of four parts. All four parts must be downloaded from the Internet or from a CD to ensure the Operating Manual is complete.



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1 Safety

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Part 4: Hygiene and disinfection for custo spiro mobile

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4.1 General notes

The cleaning and disinfection procedures depend on the risk of infection and whether or not custo spiro protect bacterial and viral filters are used. **Basically, it is recommended to use the custo spiro protect bacterial and viral filter.**

WITHOUT A CUSTO SPIRO PROTECT FILTER

After EACH examination:

- Clean and disinfect the inside and outside of the measuring head (instrument disinfection)
- Disinfect the entire device and all its components (wipe disinfection)
- Dry and calibrate the device

WITH A CUSTO SPIRO PROTECT FILTER

After EACH examination:

- Dispose of the custo spiro protect filter in a proper manner

- Disinfect the entire device on the outside (wipe disinfection)

Weekly or after 100 examinations:

- Check the device for linearity and proper functioning and calibrate it if necessary

- Disinfect the measuring head (instrument disinfection)

- Without the use of a custo spiro protect filter, custo spiro mobile and all its components have to be completely disinfected (also from the inside) after each examination. In the case of infectious patients, it must be ensured that the consumables are disposed of in a safe and proper manner.

- With the use of a custo spiro protect filter, custo spiro mobile and all its components have to be disinfected on the outside after each examination. The following must be noted:

For infectious patients:

- custo spiro mobile and all the parts that have come into contact with the patient during the examination must be disinfected on the outside.
- custo spiro protect and the nose clip must be disposed of in a proper manner.

For all other patients:

- custo spiro mobile and all the parts that have come into contact with the patient during the examination (including the nose clip), must be disinfected on the outside.
- custo spiro protect must be disposed of with general household waste.

Independent of performing cleaning and disinfection after each patient, it is recommended that all parts of the device are thoroughly cleaned and disinfected once a week.

custo spiro protect bacterial and viral filter



4.2 Important notes

Use only cleaning agents and disinfectants that have been approved by custo med. Unsuitable agents could damage the device.

The handhold of the device **b** must not be immersed in liquids.

The measuring head **a** is suitable for cleaning in an ultrasonic bath.

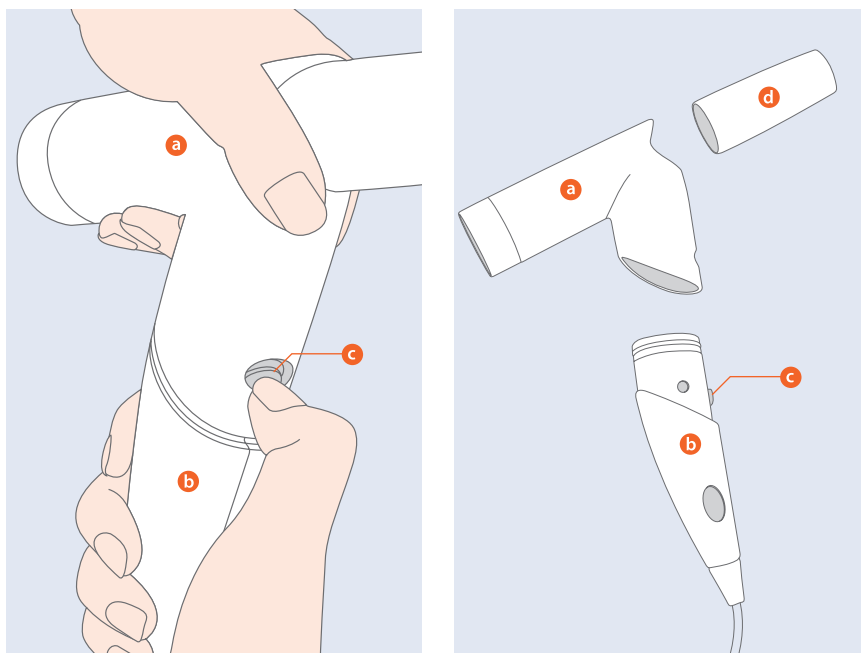
Ensure that the measuring head **a** is completely dry before the next measurement.

4.3 Cleaning and disinfection of custo spiro mobile

Disassembling custo spiro mobile for cleaning and disinfection

- Detach the measuring head **a** from the handhold **b**.
To do so, press the unlocking button **c** and detach the measuring head **a** upwards.
- Make sure that the sealing ring is not damaged.
- Draw the mouthpiece **d** out of the measuring head **a**.

Clean or disinfect as soon as possible after use.



4.4 Disinfection of the measuring head and the measuring screen

- Reprocessing type: Instrument disinfection
- Note: If necessary, carry out a pre-cleaning (e.g. ultrasonic bath). After instrument disinfection, rinse the measuring head and the mouthpiece thoroughly with deionised, distilled water. Shake the water out of the measuring head and wipe down the surfaces with a single-use cloth. Disinfectant residues must be completely removed.

4.5 Disinfection of the handhold

- Reprocessing type: Wipe disinfection
- Note: Make sure that no moisture gets inside the handhold (e.g. via the sensor).

Reassemble the device – the unlocking button must engage when the measuring head is fitted.

4.6 Disinfection of the nose clip

- Reprocessing type: Wipe disinfection

4.7 Approved cleaning agents and disinfectants

Wipe disinfection:

Meliseptol® Wipes sensitive (B.Braun)

Meliseptol® Foam pure (B.Braun) – (use with a soft, lint-free cloth)

- Note: Please observe the manufacturer's instructions

Instrument disinfection:

Helipur H plus N (B.Braun) as a solution of max. 4%

- Note: Please observe the manufacturer's instructions

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- Note: The approved disinfectants can be replaced by products from other manufacturers provided they are equivalent in terms of disinfection and material compatibility. For more information, contact your partner for hygiene and disinfection.

4.8 custo spiro protect bacterial and viral filter

When using custo spiro protect bacterial and viral filters, the necessity to clean and disinfect the pulmonary function testing device is minimised but not entirely eliminated.

A filter is only to be used for a single patient and after the examination it must be disposed of in a safe and proper manner.

4.9 Disposal of used custo spiro protect bacterial and viral filters

According to the Waste Catalogue Ordinance (WCO), contaminated bacterial and viral filters (and nose clips) are classified as waste whose collection and disposal is subject to special requirements in view of the prevention of infection and are categorised with waste code AS 18 01 03.

The disposal method also depends on the amount of contaminated waste.

- In clinics and medical practices which focus on treating patients with the corresponding diseases (e.g. active tuberculosis) (i.e. not only in sporadic individual cases), the filter and the nose clip must be disposed of in a separate container (tear-resistant, labelled with the biohazard symbol). Note the Law on the Prevention and Control of Infectious Diseases (§17 IfSG: Objects tainted with notifiable pathogens).
- In principle, this requirement also applies in the case of small quantities of contaminated waste. However, disinfection of individual parts is possible (any disinfectant, the part does not require any further consideration). You can then dispose of filters and nose clips with normal waste (domestic waste in a medical practice).

See the "Directive on the proper disposal of waste from health care facilities".



Cleaning overview at a glance

Product	Wipe disinfection	Washing with a disinfectant	Miscellaneous
custo cardio 100/110/130/300	X		
custo cardio 200/400 and electrodes			S
custo screen 300/400/pediatric	X		
Blood pressure cuff			S
custo flash 500/510/510V/501/501L	X		
custo watch	X		
custo kybe	X		
custo guard	X		
custo belt electrode belt		X	
custo belt extender		X	
custo ECG cable guard 3 /cable adapter	X		
custo spiro mobile			S
Carrying cases, carrying belt, neck strap		X	

S Special reprocessing necessary – more information can be found in the respective Operating Manual

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