Instruction for Use
simex *cuff M* and simex *cuff S*
Automated Subglottic Aspiration System

simex
Medizintechnik GmbH

CE 0843

UL CERTIFIED SAFETY US-CA E355754

AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008)

GA_CuffM-S_3rd_EN_2016-06-09_2017-04-11_Rev.C00_USA

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The safety of the **simex *cuff M* and simex *cuff S*** complies with the acknowledged rules of technology and meets the requirements of the **German Medical Devices Act**.
The **simex *cuff M* and simex *cuff S*** bear the **CE marking CE0843** in accordance with EU Council Directive 93/42/EEC concerning medical devices and meet the essential requirements of Annex I of this directive.
The **simex cuff M and simex *cuff S*** have been tested in accordance with IEC 62353.
The **quality management system** applied by simex Medizintechnik GmbH is certified in compliance with the relevant international standards.
The **simex *cuff M* and simex *cuff S*** are medical aspiration devices classified as class IIa in accordance with EU Council Directive 93/42/EEC, Annex IX.

Errors and omissions excepted.

Rx only Federal Law restricts this device to sale or rental by or on the order of a physician

Table of Contents

1 User Information

1.1 Using this Instruction Manual

Please read this entire instruction for use before operating the **simex *cuff M* or simex *cuff S*** device for the first time.
Please read the safety instructions (chapter 1.6) to avoid hazards.
This instruction for use is a component of the **simex *cuff M* and simex *cuff S***. Keep this instruction for use in an easily accessible location.
Include this instruction for use when passing the **simex *cuff M* or simex *cuff S*** device on to third parties.

1.2 Icons

1.2.1 General Symbols

Symbol	Meaning	Symbol	Meaning
	**Attention:** possible bodily injury, health risks or possible property damage.		**NOTE** Note containing useful information and tips.
	Radiofrequency - RF		MRI - Unsafe

1.2.2 Device and Packaging

Symbol	Meaning	Symbol	Meaning
	Protect from moisture		Order number
	Protection class II		Serial number
	Humidity limitation		Lot number
	Air pressure limitation		Date of manufacture
	Follow the instruction for use		Manufacturer
	Protection class: **Type BF** (Body Floating)		Do not use if packaging is damaged!
	Temperature limitation		Do not reuse
	This device must not be disposed of in domestic waste.		Power supply unit
	Keylock (symbol in display) Is activated automatically during operation and can be cancelled by simultaneously pressing the Up and Down buttons.		Federal Law restricts this device to sale or rental by or on the order of a physician.

1.2.3 Display

Symbol	Meaning
	Battery full
	Battery low
	Battery empty
	Up
	Down
	OK (On, Enter)
	Cancel (Off, Back)
	Power supply unit is connected
	Run mode
	Pause mode
	Filter run time elapsed; replacement of the internal filter by service is required!
	Alarm OFF The alarm “System closed” is inactive.

1.3 Symbol Convention

Symbol	Meaning
•	Enumeration
1. **2.**	Perform the process in the specified order.

1.4 Glossary

A

approx.	Abbreviation for “approximately”
Aspirate	Aspirate is the generic term for secretions, bodily fluids and liquids used for flushing that are typically accumulated when aspirating the upper respiratory system. It can be easily aspirated using the devices described here.

C

Contamination	Contamination means that bacteria and viruses from the aspirate have come into contact with the interior of the device.

D	
DFS®	Double filter system (only **simex *cuff S***) An external filter and a bacterial filter integrated into the aspirator make up the double filter system. The double filter system effectively protects the interior of the device from contamination and overflow. It enables safe processing and rapid reuse of the product.
E	
e.g.	For example, abbreviation for Latin “exempli gratia”
I	
incl.	Abbreviation for “inclusive”
IP22	International Protection / Protection Class The Protection Class defines the degree of protection of the device against contact and ingress of liquids. The **simex *cuff M* and simex *cuff S*** are protected against finger access and falling water drops at an inclination of up to 15°.
O	
Overflow	Overflow means that the aspirate is sucked into the interior of the device.
P	
Processing	The processing procedure is required for each new patient. The term processing denotes the process in which parts coming or potentially coming into contact with aspirate are cleaned, disinfected and replaced if necessary. The processing procedure must only be performed by simex Medizintechnik GmbH or an authorized service partner of simex Medizintechnik GmbH.

1.5 Intended Use

The **simex *cuff M* respectively simex *cuff S*** device is a network-independent mobile medical device for subglottic aspiration of secretions to be used with cuffed endotracheal and tracheal tubes with integrated subglottic suction ports.

The **simex *cuff M* respectively simex *cuff S*** must never be used simultaneously on more than one patient!

1.5.1 Essential Features

- Generation of a vacuum
- Generation of volumetric flow
- Aspiration of secretion

1.5.2 Indications

- The simex Subglottic Aspiration System is indicated for vacuum suction, extraction, aspiration and removal of surgical fluids, tissue (including bone), bodily fluids or infectious material from wounds or from patient's airway or respiratory system, either during surgey or at the patient's bedside.
- Generally, the simex Subglottic Aspiration System is intended for removing subglottic secretions from the patient´s airway above the endotracheal or tracheal cuff using intermittent suction when used in ICU and acute care settings where the duration of mechanical ventilation is limited to a maximum of 4 weeks.

1.5.3 Contraindications

The **simex *cuff M* and simex *cuff S*** Subglottic Aspiration System is not intended for continuous operation in low vacuum drainage (e.g. thoracic, wound drainage)

1.5.4 Restrictions on use

- In medical rooms where potential equalization is necessary (e.g. heart surgery)
- In hazardous areas
- Outside / outdoor

1.6 Basic Safety Instructions

CAUTION!

Health risks due to the handling of infectious liquids or pathogenic germs.

Infectious and pathogenic germs in the aspirate cause health risks.

- Always aspirate with endotracheal or tracheal tubes with integrated suction ports. The suction tube must never come into contact with the aspiration area.
- Follow the hygiene, cleaning and decontamination instructions.

WARNING!

Risk of damage due to improper power supply.

Improper operation causes overvoltage in the device which may be transmitted to the operator.

- Ensure prior to startup that the mains supply is designed to operate at supply voltages of 100-240 V alternating current.
- Ensure prior to startup in UL listed markets such as the USA and Canada that the mains supply is designed to operate at a supply voltage of 120 V alternating current.
- Only operate the device with the provided power supply unit (Type: FRIWO FW 7555M/12).

ATTENTION!

Risk of damage due to electromagnetic phenomena.

Medical electrical equipment is subject to special precautionary measures regarding electromagnetic compatibility and must be installed and operated in accordance with the EMC information provided in the accompanying documentation! (see chapter 7.3)

CAUTION!

Hazard of persons due to improper handling.

- Use the device for its intended purpose only.
- Never use the device for wound treatment.
- Never use the device for thorax drainage.
- When using the power supply unit, make sure the power supply unit is connected to the mains supply (100 V -240 V AC) only after the power cord plug of the power supply unit has first been connected to the suction device.
- The separation of the power supply unit from the mains supply must occur in exactly the opposite sequence (first separate the power supply unit from the mains supply (100 V - 240 V AC) and then the power cord plug from the suction device).

ATTENTION!

Damage to the device due to improper handling.

- Never aspirate flammable, corrosive or explosive liquids or gases.
- Do not drop the device.
- Do not use the device in case of apparent housing damage.

CAUTION!

Safety defects due to improper accessories and spare parts.

The use of accessories and spare parts other than those recommended by simex Medizintechnik GmbH may compromise the safety and function of the device. Damage caused by using non-recommended accessories and spare parts or by improper use is not covered by warranty in any case.

- Only use original accessories and spare parts.

ATTENTION!

Damage to the device by ingress of liquids.

- Do not use the device near splashing water.
- Do not use the device in damp rooms or while bathing or showering.
- Do not allow the power supply unit, plug and display film to get wet.
- Never submerge the device in water or other liquids (also not while not in operation).

ATTENTION!

Damage to the device by heat.

- Do not cover the power supply unit.
- Keep the device as well as the power cord and power supply unit away from other heat sources.

⚠ **CAUTION!**	**Hazard of persons due to strangulation.** People may strangle themselves on the tubing or the power cord. • Store the device incl. accessories in the shipping carton. • To prevent misconnections, always trace the tubing to the point of origin before connecting to a device or port. Recheck connections and all patient tubes upon the patient's arrival to a new setting or service .
⚠ **ATTENTION!**	**Known or identifiable conditions for medical care within a domestic environment.** • Children and pets must be kept away from the device to ensure that the device is not knocked over or dropped. • Prior to connecting the power supply unit, ensure that the voltage of the device corresponds to the domestic power supply. • Do not use the device in damp rooms, baths or showers. • Do not allow the power supply unit, plug and switch unit to get wet. • Never submerge the device in water or other liquids (also do not submerge while not in operation). • Incident light may effect the readability of the display negatively.

1.7 User Requirements

The **simex *cuff M* or simex *cuff S*** device must only be operated and used by instructed and trained personnel.
Familiarize yourself with the functions of the **simex *cuff M* or simex *cuff S*** device prior to startup.

Training on the operation of **simex *cuff M* and simex *cuff S*** is provided by simex Medizintechnik GmbH or an authorized distribution partner of simex Medizintechnik GmbH. Product training takes approximately one to two hours and includes an explanation of the design and function of the device, the handling of the device, the alarm system, the cleaning and disinfection as well as the procedure to be followed for each new patient and for disposal.
Training should be repeated on a regular basis every 24 months.
Each participant receives a certificate as proof of training.

1.8 Information on Product Liability

The liability for the operation of the device is channeled to the operator in the following cases:

- the device is used outside its intended use,
- the device is not used in accordance with the instruction for use,
- the device is opened by unauthorized personnel,
- installation, settings, enhancements, routine maintenance or repairs are performed by unauthorized personnel,
- original accessories and spare parts have not been used

1.9 Material Compatibility

⚠ **ATTENTION!**	**Aggressive substances may damage the device and the accessories.** • Please follow the cleaning and care instructions (chapter 4.1)

2 Product Description

2.1 Whole View

2.1.1 simex *cuff M*

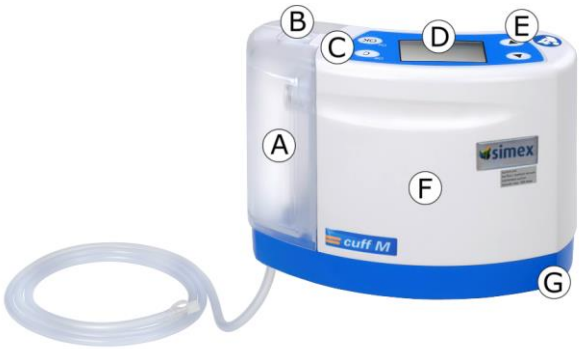


Fig. 1 simex cuff M

A Disposable secretion canister (250 ml) with integrated suction tube
B Canister locking mechanism
C OK (On) and C (Off) buttons
D Display
E ▲ and ▼ arrow buttons
F **simex *cuff M*** device Socket
G for power supply unit

2.1.2 simex *cuff M* product contents

- the device **simex *cuff M***
- instruction for use
- 2 x disposable secretion canister (250 ml) with integrated bacterial filter, carbon filter, solidifier and suction tube
- power supply unit (Type: FRIWO FW 7555M/12) incl. country adapter
- multilingual charging instructions
- instructions for safe handling of battery packs
- "Used Medical Device" label and decontamination certificate
- test report according to IEC 62353
- optional accessories (depending on the order)

2.1.3 simex *cuff S*

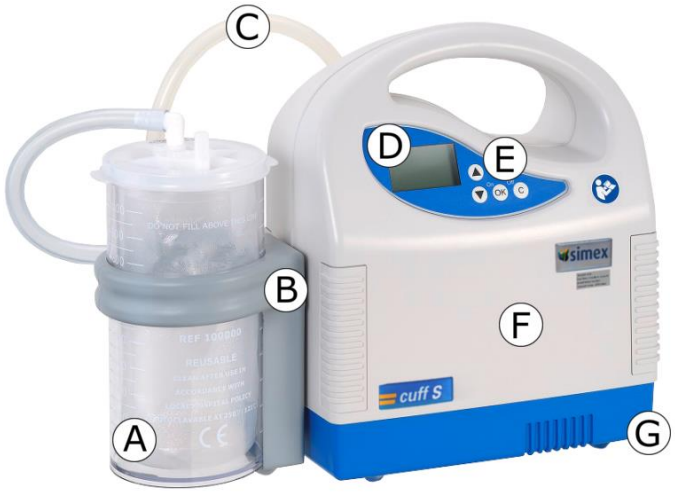


Fig. 2 simex cuff S

A	Disposable secretion canister system (1,000 ml)
B	Holder for external canister
C	Connecting tube
D	Display
E	Control panel (OK (On) and C (Off) buttons and ▲ and ▼ arrow buttons)
F	**simex *cuff S*** device
G	Socket for power supply unit

2.1.4 simex *cuff S* product contents

- the device **simex *cuff S***
- instruction for use
- disposable secretion canister system
  (comprising the external canister, disposable liner, holder for external canister, connecting tube and disposable suction tube (sterile))
- power supply unit (Type: FRIWO FW 7555M/12) incl. country adapter
- multilingual charging instructions
- instructions for safe handling of battery packs
- "Used Medical Device" label and decontamination certificate
- test report according to IEC 62353
- optional accessories (depending on the order)

2.2 Product Properties

CAUTION!	**Hazard of persons due to improper handling.** • Use the device for its intended use only. • Never use the device for aspiration in low vacuum range (e.g. thorax drainage).
ATTENTION!	**Damage to the device due to improper handling.** • Never aspirate flammable, corrosive or explosive liquids or gases! • Do not drop the device! • Do not use the device in case of apparent housing damage.

The **simex *cuff M* respectively simex *cuff S*** device is a portable aspirator for stationary and in the medical, subglottic aspiration of secretion in combination with endotracheal and tracheal tubes with integrated subglottic suction port. It is intended for aspiration in the middle vacuum range and can be used in the hospitals.
The **simex *cuff M* and simex *cuff S*** devices are lightweight, portable aspirators. They are operated via the internal battery or via the supplied power supply unit that also can be used to recharge the battery.
The vacuum is generated by a maintenance free electric motor driven membrane pump. After it is switched on, the vacuum pump creates a vacuum in the tubing system and disposable secretion canister, which is used to aspirate fluids (with endotracheal and tracheal tubes with integrated subglottic suction port). The secretion is directed away from the patient and collected in the disposable secretion canister. If the disposable secretion canister is full, the device triggers the "System closed – canister full" alarm via an integrated overflow protection system and stops the pump. The **simex *cuff M* and simex *cuff S*** devices must only be operated with the supplied disposable secretion canister (system).

The provided disposable secretion canister for the **simex *cuff M*** as well as the disposable liner and the suction tube for the **simex *cuff S*** are intended for single use.

2.2.1 Disposable secretion canister for simex *cuff M*

The disposable secretion canister consists of a canister with a connected suction tube. The disposable secretion canister has an integrated bacterial filter, carbon filter and solidifier. The hydrophobic bacterial filter integrated in the disposable secretion canister is 99.999% effective against bacteria and viruses. This integrated filter prevents an overflow in the event of an operational error. If the liquid reaches this filter, aspiration is no longer possible and the error message "System closed – canister full" appears on the display. The aspiration process is discontinued. The disposable secretion canister must be replaced.
The activated carbon filter in the disposable secretion canister reduces the spread of odor.

Solidifier:
Disposable secretion canisters filled with aspirate can be transported and disposed in a leak-proof manner by using the solidifier. The aspirate solidifies after an average gelling time of 2 to 5 minutes (depending on the consistency of the aspirate), irrespectively of the aspiration intervals.

The **disposable secretion canister incl. the suction tube** is intended for **single use**. Replace the disposable secretion canister in accordance to the respectively applicable hygiene instructions, if it is full, prior to each new patient or weekly at the latest.

2.2.2 Information on the simex filter system for the simex *cuff M*

The filter system of the **simex *cuff M*** consists of the external bacterial filter integrated in the disposable secretion canister and the internal filter installed in the device. The internal filter is a self-sealing bacterial filter and is 99.999% effective against bacteria and viruses in combination with the integrated filter in the disposable secretion canister.

The simex filter system effectively protects the interior of the device from contamination and overflow.

Service life and reuse

The internal filter is not intended for reuse. To ensure consistent performance, the internal filter must be replaced after contact with the secretion (blocked), after the filter service life has expired ([!] symbol in the display) or during maintenance / repair.

The internal filter must be replaced by simex Medizintechnik GmbH or an authorized service partner of simex Medizintechnik GmbH.

2.2.3 Information on the carbon filter of the simex *cuff M*

An additional filter in the exhaust air vent of the **simex *cuff M*** removes undesirable odor out of the exhaust air of the device. This filter consists of a thin activated carbon coated nonwoven. The activated carbon in the nonwoven adsorbs the odor particles of the exhaust air and neutralizes them. Spreading of odor will be effectively reduced.

Service life and reuse

The carbon filter is not intended for reuse. To ensure consistent performance, the carbon filter must be replaced during maintenance / repair or after 2 years at the latest.

The carbon filter must be replaced by simex Medizintechnik GmbH or an authorized service partner of simex Medizintechnik GmbH.

2.2.4 Disposable secretion canister system for simex *cuff S*

The disposable secretion canister system consists of the external canister and the disposable liner. The disposable liner has an integrated bacterial filter, carbon filter and solidifier. The self-sealing bacterial filter integrated in the disposable liner is 99.999% effective against microorganisms. This integrated filter prevents an overflow in the event of an operational error. If the liquid reaches this filter, aspiration is no longer possible and the error message "System closed – canister full" appears on the display. The aspiration process is discontinued. The disposable liner must be replaced.
The activated carbon filter in the disposable liner reduces the spread of odor.

Solidifier:
Disposable liners filled with aspirate can be transported and disposed in a leak-proof manner by using the solidifier. The aspirate solidifies after an average gelling time of 2 to 5 minutes (depending on the consistency of the aspirate), irrespectively of the aspiration intervals.

The **disposable liner and the suction tube** are intended for **single use**. Replace the disposable liner incl. suction tube in accordance to the respectively applicable hygiene instructions, if it is full, prior to each new patient or weekly at the latest.

2.2.5 Information on the double filter system for simex *cuff S*

The simex double filter system DFS® consists of the external bacterial filter integrated in the disposable liner and the internal filter installed in the device. The filters are hydrophobic and self-sealing bacterial filters, which, in combination, are 99.999% effective against bacteria and viruses.
The internal bacterial filter is installed in the **simex *cuff S***.
The external bacterial filter is incorporated in the disposable liner.

The simex double filter system DFS® effectively protects against overflow and contamination of the interior of the device. It permits fast, simple and cost-effective maintenance.

Service life and reuse

The internal filter of the simex double filter system DFS® as well as the disposable liner are not intended for reuse. To ensure consistent performance, the internal filter must be replaced after contact with the secretion/aspirate (blocked), after the filter service life has expired ([!] symbol in the display) or during maintenance / repair.

The internal filter must be replaced by simex Medizintechnik GmbH or an authorized service partner of simex Medizintechnik GmbH.

2.2.6 Battery

The charge level of the battery is shown in the display.

It is strongly recommended to fully charge the battery prior to first startup of the **simex *cuff M* respectively simex *cuff S*** and to repeat this after the first uses.

The **simex *cuff M* and simex *cuff S*** are equipped with a lithium-ion battery, which, unlike traditional types of rechargeable batteries, has a low self-discharge rate.

The **simex *cuff M* and simex *cuff S*** device should ideally be stored and charged at room temperature in accordance with the ambient conditions specified in the technical data. Never store the device incl. battery in a discharged state!
Fully recharge the battery if the device is not operated for a longer period of time (approx. 10 months).

Lithium-ion rechargeable batteries do not have a memory effect. They can, therefore, be recharged at any time after initial charging.
Only frequent short-time charging should be avoided.

The battery of the **simex *cuff M* and simex *cuff S*** is protected against deep discharge, but the charging information listed above must nevertheless be followed. The battery is also protected against overheating during charging. If the battery temperature is exceeded during charging due to improper ambient conditions, charging is temporarily discontinued to allow cooling. The purpose of this measure is to ensure safe operation and to protect the battery.

The operational service life of the battery is 2 years. According to the manufacturer of the battery, the battery has a remaining capacity of more than 80% after 300 charge cycles.

2.2.7 Pressure settings

Once the **simex *cuff M* or simex *cuff S*** has been switched on, the pressure settings can be individually adjusted by a healthcare professional.

The pressure settings can be adjusted in a range from -60 mbar to -300 mbar (in steps of 10 mbar). -120 mbar is factory preset pressure.
The change of pressure setting can also be performed during operation.

Always use the lowest possible pressure setting. Adjustments to device settings must only be made if instructed to do so and only by healthcare professionals.
Prior to switching on the **simex *cuff M* or simex *cuff S*** it must be ensured that the device is equipped with a disposable secretion canister.

CAUTION!

Follow the maximum pressure setting recommended by the manufacturer of endotracheal (ETT) or tracheal (TT) tube with integrated suction lumen. In addition follow the manufacturers instructions for use of the ETT and TT tubes used with simex ***cuff M*** and ***cuff S***.

2.3 Warranty

The devices of simex Medizintechnik GmbH are covered by warranty for 2 years. It is neither extended nor renewed by warranty work.
The battery is covered by warranty for 6 months.
Wearing parts are excluded from the warranty.

simex Medizintechnik GmbH is responsible for impacts on safety, reliability and specified performance only if:

- original simex accessories and spare parts are used,
- maintenance and repair are performed by professionals authorized by simex Medizintechnik GmbH or by simex Medizintechnik GmbH itself,
- the affected product is used and operated in accordance with the instruction for use and within its intended use.

simex Medizintechnik GmbH does not warrant accurate function of the devices **simex *cuff M* and simex *cuff S*** and is not liable for a loss of property or personal injury in the following circumstances:

- no original simex accessories or spare parts are used,
- using information of this instruction for use are ignored,
- installation, settings, changes, upgrades or repairs are not carried out by simex Medizintechnik GmbH or by professionals authorized by simex Medizintechnik GmbH,
- the safety seal is broken or removed.

All warranty claims are voided if the device is opened by unauthorized personnel, the safety seal is removed / damaged or repairs have been performed by unauthorized personnel.

3 Operation

CAUTION!

Hazard of persons due to improper handling.

- Use the device for its intended purpose only.
- Read chapter 3.1 to 3.4!
- Perform the aspiration in the respiratory area only after instruction by trained personnel!
- Use exclusively endotracheal and tracheal tubes with suction port for aspiration!

ATTENTION!

Malfunction due to aspirated secretions.

- Ensure that the disposable secretion canister (250 ml) of the **simex *cuff M*** and the disposable liner (1,000 ml) of the **simex *cuff S*** is replaced on a regular basis. If the disposable secretion canister respectively the disposable liner is full, the integrated overflow protection system is triggered and the alarm "System closed – canister full" is activated. This disrupts the aspiration process.
- Switch off the device when replacing the disposable secretion canister respectively the disposable liner.
- If the internal filter of the **simex *cuff M*** or the DFS® of the **simex *cuff S*** is blocked, the device must be properly processed by simex Medizintechnik GmbH or by an authorized service partner of simex Medizintechnik GmbH!

WARNING!

Hazard of persons during operation in a domestic environment.

Due to the increasing mobility of patients in a domestic environment, there is an increasing risk of forming leaks or blockages in the tube system.
For this reason, a detailed training and instruction of patients as well as performing regular monitoring of the tubing and aspiration system by trained personnel is mandatory.

3.1 Set-Up and Startup

3.1.1 Startup

It is important to follow the safety instructions in chapter 1.6 prior to initial startup.
Always have one backup disposable secretion canister (250 ml) for the **simex *cuff M*** and one backup disposable liner (1,000 ml) for the **simex *cuff S*** ready, since it is absolutely necessary for safe operation!

- Remove the device and the accessories from the packaging.
- Please read this entire instruction for use before operating the **simex *cuff M* or simex *cuff S*** device for the first time.
- Always place the device on a sturdy and flat surface, take care of the correct position of the device.
- Fully charge the battery prior to initial startup.
- Inspect all tubings as well as the power supply unit for damage prior to each startup of the **simex *cuff M* respectively simex *cuff S***. It is important to avoid kinking when connecting the tubing. Ensure prior to switching on the unit that the disposable secretion canister and tubings are properly connected.
- Perform a function test! (Please refer to chapter 5.1)

3.1.2 Connecting the simex *cuff M* and simex *cuff S*

Use the socket for power supply unit of the **simex *cuff M*** (chapter 2.1.1, fig. 1 (G)) or the socket for power supply unit of the **simex *cuff S*** (chapter 2.1.3, fig. 2 (G)) to connect the device to the mains power supply via the supplied power supply unit (type: FRIWO FW 7555M/12) for charging or operation as required.
Use the supplied power supply unit only. First connect the power supply unit to the socket for power supply unit of the **simex *cuff M* or simex *cuff S*** and then to the mains power supply.

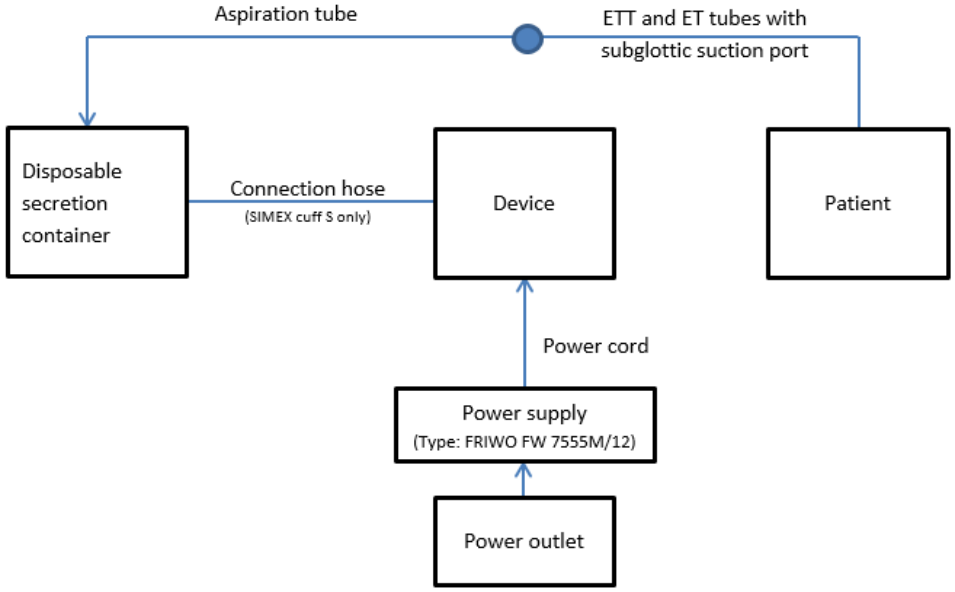


Fig. 3 Connecting the simex cuff M and simex cuff S to the patient and accessories

3.1.3 Positioning of the simex *cuff M*

The **simex cuff M** can be placed next to the patient's bed or attached by means of a variable holder for tube and rail systems. An optional carrying bag is available for portable use. It is, however, up to the physician to decide whether the condition of the patient permits portable use. The **simex *cuff M*** can also be used in a horizontal position:

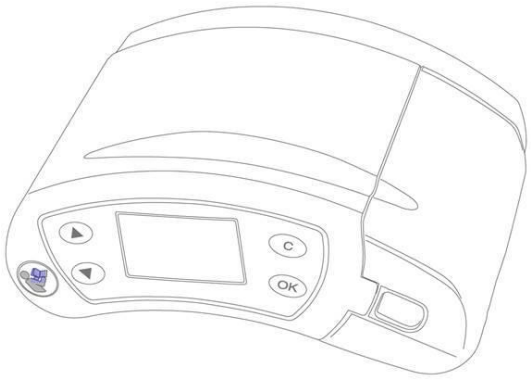


Fig. 4 simex cuff M horizontally

To ensure optimum aspiration of the secretions, place the **simex *cuff M*** below the suction point. It should be noted that the suction tube does not form a dip/loop and is situated at least on patient level.

3.1.4 Connecting the disposable secretion canister (250 ml) of the simex *cuff M*

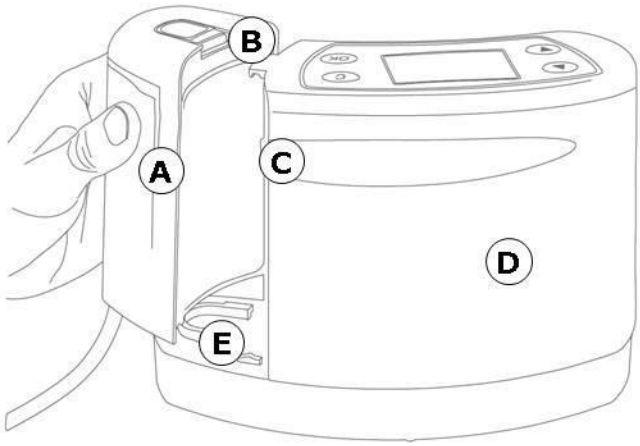


Fig. 5 Connecting the disposable secretion canister

A Disposable secretion canister (250 ml) incl. suction tube
B Locking mechanism for canister
C Aspiration port
D **simex *cuff M***
E Guiding rail

1. Remove the disposable secretion canister (250 ml) (fig. 5 (A)) from the packaging.
2. Slide the canister on the guiding rails (fig. 5 (E)) of the **simex *cuff M*** until the disposable secretion canister clicks into place in the locking mechanism (fig. 5 (B)).
3. Connect integral suction tube of canister with a sterile suction tube to ETT or ET suction port.

3.1.5 Positioning of the simex *cuff S*

The **simex *cuff S*** can be placed next to the patient's bed. Optionally, a variable holder for attachment of the device to tube and rail systems as well as a bed holder is available.

To ensure optimum aspiration of the secretions, place the **simex *cuff S*** below the suction point. It should be noted that the suction tube does not form a dip/loop and is situated at least on patient level.

3.1.6 Connecting the simex disposable secretion canister system of the simex *cuff S*

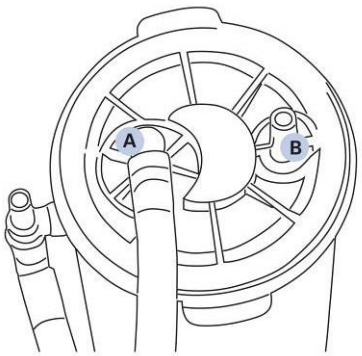
ATTENTION!

Malfunction due to collapsing disposable liner.

A leak in the external canister or at the lid of the disposable liner may cause air to flow into the external canister. This may lead to the collapse of the disposable liner.

- Inspect the disposable secretion canister system (1,000 ml) to ensure that the lid of the disposable liner is firmly connected to the external canister.
- Ensure that all connections are firmly attached and properly connected.
- Ensure that the external canister is undamaged and the T-piece is firmly attached.
- Follow the instruction for use supplied by the manufacturer!

The original simex disposable secretion canister system consists of the external canister, the holder for the external canister, the disposable liner, the connecting tube for the disposable liner and the sterile disposable suction tube with step connector.



Connection designation

A Vacuum connection
B Patient connection

Please also follow the instruction for use supplied with the disposable secretion canister system (1,000 ml)!

Fig. 6

1. Remove the disposable liner from the packaging and fully extend it.

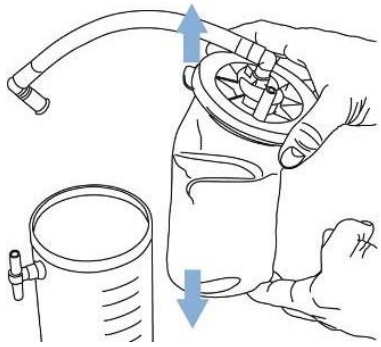


Fig. 7

2. Place the disposable liner in the reusable external canister. Press the lid's edges firmly down to ensure proper sealing.

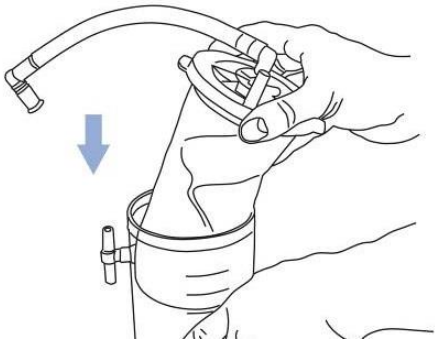


Fig. 8

3. Attach the prefitted connecting tube of the disposable liner to the bottom end of the T-piece located at the external canister.

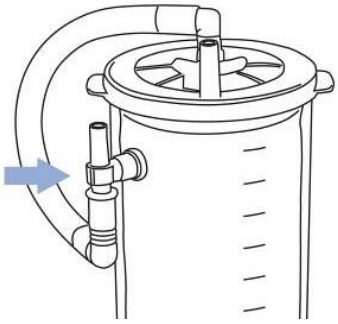


Fig. 9

4. Connect the vacuum connection of the device with the corresponding vacuum connection of the external canister (top end of the T-piece). Use the supplied connecting tube to do so.

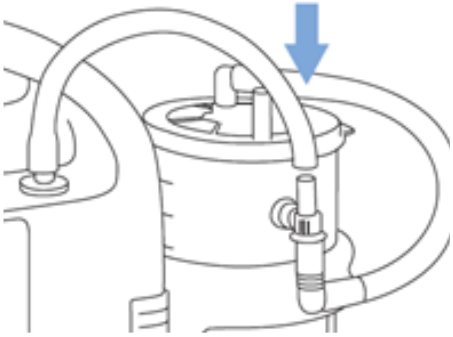


Fig. 10

5. Connect the patient connection of the disposable liner (fig. 6 (B)) to the suction tube.

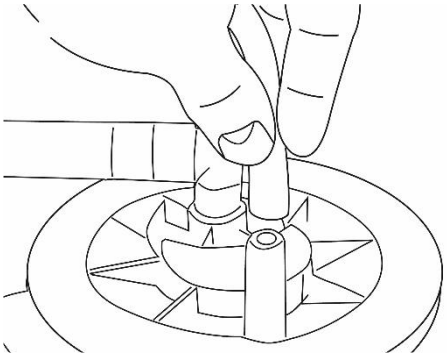


Fig. 11

3.1.7 Connecting endotracheal and tracheal tubes with integrated suction port

Connect the suction tube of the disposable secretion canister to the integrated suction port of endotracheal and tracheal tubes.

The suction tube must never come into direct contact with the aspiration area.

3.2 Operation of the simex *cuff M* and simex *cuff S*

1. Press the OK button for 1-2 seconds to switch on the **simex *cuff M* or simex *cuff S***. The following start screen is displayed for 5 seconds:

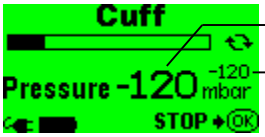
2. The following screen is displayed:
(preset of the target value: -120 mbar)

3. Use the ▲▼ arrow buttons to set the prescribed vacuum value (target value).

CAUTION!

Maximum pressure must not exceed -200mbar or -150mmHg. The recommended guidelines for pressure ranges for adults is -106 to -200mbar or -80 to -150 mmHg. The pressure setting in children is not known, but should not exceed -106mbar or -80 mmHg. In case of blockage of secretion fluids in the suction lumen of ETT or TT cuffed tubes, the medical professional may increase the pressure settings from between -200 up to -300mbar to clear the blockage and then return back to the recommended lower pressure settings.

4. Press the OK button to start the therapy. 2 values are shown in the display.

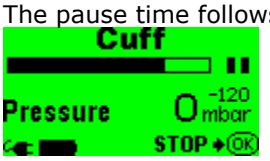


Actual value

Target value

The bar in the upper display section fills in from the left to the right and shows the run time.

The pause time follows subsequent to the run time.



The bar in the upper display section moves from the right to the left and shows the pause time.

5. Press the OK button to stop the therapy.

6. You will get back to the overview screen:

7. Switch off the **simex *cuff M* or simex *cuff S*** by pressing the C button for 3 seconds.

To aspirate without pause in case of a high rate of secretion or during flushing, press the OK button two times at the beginning of the pause time to skip the pause. If necessary repeat this step.

3.2.1 Setting the run and pause time

The **simex cuff M and simex cuff S** enable the selection of run and pause time at initial startup. The selected values are stored and automatically loaded at each startup. To customize the time settings, follow these steps:

1. Press the OK button for 1-2 seconds to switch on the **simex *cuff M* or simex *cuff S***. The following start screen is displayed for 5 seconds:

2. While the start screen is displayed, simultaneously press the ▲▼ arrow buttons. The menu *Setup* is displayed.

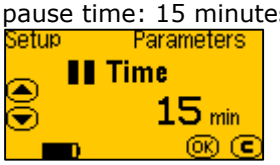
3. Select the menu Parameters with the ▲▼ arrow buttons.

4. Use the OK button to confirm your choice.

5. Use the ▲▼ arrow buttons to set the prescribed run time [sec.]. The minimum run time is 10 seconds and the maximum run time is 60 seconds (in steps of 1 second, preset run time: 20 seconds).

6. Use the OK button to confirm your choice.

7. Use the ▲▼ arrow buttons to set the prescribed pause time [min]. The minimum pause time is 3 minutes and the maximum pause time is 60 minutes (in steps of 1 minute, preset pause time: 15 minutes).



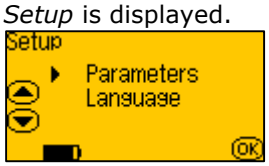
8. Use the OK button to confirm your choice.

3.2.2 Language selection

The **simex *cuff M* and simex cuff S** enable the selection of a language at startup. The selected language is stored and automatically loaded at each startup. To customize the language, follow these steps:

1. Press the OK button for 1-2 seconds to switch on the **simex *cuff M* or simex *cuff S***. The following start screen is displayed for 5 seconds:

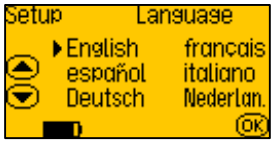
2. While the start screen is displayed, simultaneously press the ▲▼ arrow buttons. The menu *Setup* is displayed.



3. Use the ▲▼ arrow buttons to select the *Language* menu.

4. Use the OK button to confirm your choice.

5. Use the ▲▼ arrow buttons to select the desired language:



6. Use the OK button to confirm your choice.

3.3 Patient Mode

The **simex *cuff M* and simex *cuff S*** enable the selection of the patient mode at startup. In patient mode, the patient runtime can be viewed and reset as well as the alarm "System closed" can be disabled or enabled.
The alarm "System closed" is generally enabled at delivery. It is intended for monitoring the aspiration flow and for signaling blockage in the tubing system or the suction port of ETT or TT tube. If the alarm is disabled manually, the setting will be saved for the next startup.
To select the patient mode, follow these steps:

1. Press the OK button for 1-2 seconds to switch on the **simex *cuff M* or simex *cuff S***. The following start screen is displayed for 5 seconds:

2. While the start screen is displayed, press and hold down the C button and additionally press the OK button for 1-2 seconds. The *Authorization* screen is displayed.

3. Use the ▲▼ arrow buttons to enter the "1000" code.
Press the ▲ arrow button until the desired digit of the code is displayed and confirm the entry with the OK button. Select the other digits of the code with the ▲ arrow button and confirm them with the OK button as well.

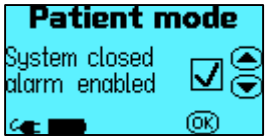
The authorization code may only be passed to specially trained personnel. You will get the training and the authorization code by simex Medizintechnik GmbH or an authorized distribution partner of simex Medizintechnik GmbH.

Passwords must be treated as confidential information to prevent misuse.

4. After the authorization, the patient runtime is displayed.

5. Press the C button for 3 seconds to reset the patient runtime to zero.

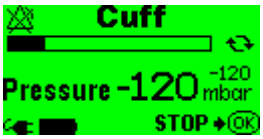
6. Press the OK button to get to the following screen for enabelling the alarm "System closed":



7. Press the ▲▼ arrow buttons to enable or disable the alarm "System closed".

   If the alarm "System closed" is disabled this setting will be shown in the display as followed:

Overview screen



Run time

Pause time

Note that monitoring of the aspiration flow and detection of blockage in the suction system is no longer recognizable by the user if the alarm "System closed" is disabled. The pressure in the pause time will be monitored and the system will be ventilated automatically if the pressure drop is too less even in case of the disabled alarm. But it is no longer apparent by the user that necessary counteractive actions cannot be carried out.

8. Exit the patient mode by pressing the OK button.

3.4 Canister replacement

3.4.1 Replacement of the disposable canister (250 ml) of the simex *cuff M*

1. Switch off the **simex *cuff M***.
2. Close the tubing clamp of the suction tube (fig. 3).
3. Separate the suction tube from the suction port of the ETT or TT tube.
4. Press on the locking mechanism at the top of the canister (fig. 5 (B)) and keep it pressed while pulling the disposable secretion canister horizontally away from the device.
5. Dispose of the disposable secretion canister and the integrated suction tube in a properly manner. (Please refer to chapter 6.3 "Disposal")
6. Place a new disposable secretion canister on the device according to chapter 3.1.4. Ensure that the disposable secretion canister is properly connected to the device.
7. Connect the suction tube to the suction port of the ETT or TT tube.
8. Switch on the **simex *cuff M***.

3.4.2 Replacement of the disposable liner (1,000 ml) of the simex *cuff S*

1. Switch off the **simex *cuff S***.
2. Close the tubing clamp of the suction tube (fig. 3).
3. Remove the suction tube from the suction port of the ETT or TT tube.
4. Separate the pre-assembled connecting tube of the disposable liner at the bottom end of the T-connector of the external canister.
5. Remove the disposable liner from the reusable external canister.
6. Dispose of the disposable liner incl. the suction tube in a properly manner. (Please refer to chapter 6.3 "Disposal")
7. Place a new disposable liner in the reusable external canister as specified in 3.1.6. Ensure that the connecting tube as well as the lid of the disposable liner are properly seated on the external canister.
8. Attach a new suction tube to the patient connection of the disposable liner and connect it to the suction port of the ETT or TT tube.
9. Switch on the **simex *cuff S***.

4 Maintenance

4.1 Cleaning and Care

4.1.1 General Information

CAUTION!

Health risks due to the handling of infectious or pathogenic germs.

Infectious and pathogenic germs in the aspirate cause health risks.

- Wear appropriate disposable gloves when replacing the disposable secretion canister or the disposable liner .
- Use the disposable secretion canister or the disposable liner for one patient only.
- Replace the disposable secretion canister (**simex *cuff M***) or respectively the disposable liner incl. suction tube (**simex *cuff S***) in accordance to the respectively applicable hygiene instructions, if it is full, prior to each new patient or weekly at the latest.
- For each new patient, processing by simex Medizintechnik GmbH or an authorized service partner of simex Medizintechnik GmbH is strictly required!
- Components that have come into contact with the aspirate/secretion must be cleaned, disinfected or disposed of after each aspiration.
- The disposal of aspirate and contaminated components must be performed in a properly manner.

CAUTION!

Health risks due to the handling of disinfectants.

- The use of appropriate disposable gloves during disinfection is recommended.
- Follow the manufacturer's disinfectant instructions.

CAUTION!

Possible bodily injury by electric shock.

- Prior to cleaning / disinfection, switch off the **simex *cuff M* or simex *cuff S***.
- Disconnect the power supply unit by unplugging it from the power supply. Disconnect the power supply unit from the socket for power supply unit of the **simex *cuff M* or simex *cuff S***.

ATTENTION!

Risk of damage to the device due to improper cleaning agents.

- Do not use disinfectants that contain acetone. These may damage or disfigure the housing components and the accessories.
- Follow the instruction for use provided by the manufacturers of the utilized disinfectants particularly with respect to material and surface compatibility as well as the concentration information.
- simex Medizintechnik GmbH recommends `Sekusetp® aktiv´ for immersion disinfection of the accessories and `Incidin® Plus´ respectively `Incidin® Liquid´ for wipe disinfection of the device.

Disinfection is not mandatory if the device is used for one patient only (in in-home care).
Disinfection is mandatory if used in an inpatient setting!

4.1.2 Cleaning and disinfection of the surface of the device

- Clean on a regular basis and disinfect in accordance to the respectively applicable hygiene instructions, at least once a week the surfaces of the device.
- The devices can be wiped with a damp, lint-free cloth.
- Follow the information on wipe disinfection provided in the previous chapter 4.1.1.

Minor discolorations may occur on the plastic housing components after prolonged use. These do not affect the function of the device, however.

If the interior of the device comes into contact with liquid, the device must be inspected by simex Medizintechnik GmbH or an authorized service partner of simex Medizintechnik GmbH.

4.1.3 Disposal of the disposable secretion canister for simex cuff M

1. Close the suction tube of the disposable secretion canister by using the closure cap of the suction tube.
2. Dispose of the disposable secretion canister incl. suction tube in a properly manner (please refer to chapter 6.3). It is a single-use item.

4.1.4 Disposal of the disposable liner and the suction tube for simex cuff S

1. Close the tubing clamp at the suction tube (fig. 3).
2. Separate the pre-assembled connecting tube of the disposable liner at the bottom end of the T-piece of the external canister.
3. Remove the disposable liner from the reusable external canister.
4. Dispose of the disposable liner incl. the suction tube in a properly manner (please refer to chapter 6.3 "Disposal").

4.1.5 Cleaning / disinfection of the external canister for simex cuff S

Please note the respectively applicable hygiene instructions. Unless otherwise directed, please follow these steps:

1. Rinse the external canister under running water.
2. Immerse the external canister in disinfectant at the specified concentration.
3. Subsequently rinse the external canister thoroughly and allow it to dry.

You may also autoclave the external canister at 121°C for 20 minutes.

simex Medizintechnik GmbH recommends to replace the external canister **every four weeks** at the latest and for each new patient.

4.1.6 Cleaning / disinfection of the tubing accessories for simex cuff S

Dispose of **all** tubing intended for single use!
Please note the respectively applicable hygiene instructions. Unless otherwise directed, please follow these steps:

1. Flush the connecting tube or place it in the disinfectant solution recommended by simex Medizintechnik GmbH for immersion disinfection.
2. Subsequently rinse the connecting tube thoroughly and allow it to dry.

simex Medizintechnik GmbH recommends to replace the connecting tube **every four weeks** at the latest and for each new patient.

4.2 Maintenance and Service

The **simex *cuff M* and simex *cuff S*** devices are maintenance-free if used according to the instruction for use.

Perform a visual and functional inspection prior to each use (please refer to chapter 5.1). Also include the accessories of the device in the inspection.

Opening of the device and repairs must only be performed by simex Medizintechnik GmbH or by authorized professionals of simex Medizintechnik GmbH in compliance with the service documentation specified by the manufacturer as well as with technical and hygienic precautionary measures.

The device may be sent back for repair to Medizintechnik simex GmbH directly or via the specialty dealer from which the device was purchased.

Clean and disinfect all accessories prior to returning the device. The device itself must be treated with a surface disinfectant. Please note the guidelines referring to decontamination before shipping (chapter 6.1).

simex Medizintechnik GmbH neither ensures proper functioning of the **simex *cuff M* and simex *cuff S*** medical suction devices nor is simex Medizintechnik GmbH liable for property damage or personal injury if

- original simex accessories or spare parts are not used,
- the user instructions in this instruction for use have not been followed,
- installation, settings, modifications, enhancements and repairs are not performed by simex Medizintechnik GmbH or authorized personnel of simex Medizintechnik GmbH,
- the safety seal has been removed or is damaged.

4.3 Testing of the simex cuff M or simex cuff S

simex Medizintechnik GmbH offers its partners and customers fast and proper maintenance as well as required testing services.

5 Problem Solving

5.1 Function Test

Perform a function test of the device without the connected canister prior to use in therapy.
Perform the following steps to do so:

1. Switch on the device as described in 3.2.
2. Start the therapy and allow the device to run in free flow. It must not occur an alarm.
   If the alarm "System closed – canister full" occurs, the internal filter of the **simex *cuff M* or simex *cuff S*** is blocked and should be replaced by service personnel.

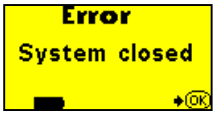
5.2 Troubleshooting

Malfunction	**Probable causes**	**Remedy**
Device does not start	• Battery is empty	• Connect the power supply unit
Therapy does not start, no flow of aspirate	• Tubing clamp is closed • Overflow protection system is blocked (disposable secretion canister or disposable liner is full) • Internal filter is blocked • Device is still in the *Setup* mode	• Verify proper connection of the tubing • Replace disposable secretion canister (250 ml) (for **simex *cuff M***) • Replace disposable liner (1,000 ml) (for **simex *cuff S***) • Please contact service. • Finalize the selection (please refer to 3.2) and start the device.

Contact the simex Medizintechnik GmbH or your service partner if the malfunction cannot be corrected by the described measures.

5.3 Error Messages

- The alarms are solely system-triggered alarms, since these are identified by the monitoring of device-specific variables.
- All alarm messages (excepting "Internal error") must be confirmed by pressing the OK button.
- Alarm messages of high priority are shown in the display with a red blinking background and the beeper is sounded (3x, pause, 2x, pause, 3x, pause, 2x) every 3 seconds.
- Alarm messages of low priority are shown in the display with a static yellow background and the beeper is sounded periodically (2x) every 16 seconds.

Error message	Status	Probable cause	Remedy
	Pump off. Discontinuation of the current operating mode.	-Disposable secretion canister (250 ml) or disposable liner (1,000 ml) is full. -If the alarm is displayed even if the canister is not connected, the internal bacterial filter is blocked.	-Switch off the device. Replace the disposable secretion canister (250 ml) or the disposable liner (1,000 ml). -Contact your service partner!
	Pump off. Discontinuation of the current operating mode.	Battery is empty.	Connect the power supply unit.
	Pump off.	Internal error.	Plug in the power supply unit and quickly unplug again. If the error reoccurs 60 seconds after restarting, contact your service partner!
* 	Pump off. Discontinuation of the current operating mode.	-ETT or TT tube is blocked. -Aspiration flow obstructed. (tubing is kinked, tubing clamp is closed or stenosis in the tubing).	-Check positioning of the ETT or TT tubes respectively the cuff pressure. -Check the tubing.
	Current operating mode continues to run in the background.	Low battery charge level.	Connect the power supply unit soon.
	(Alarm after 15 minutes)	-The therapy was not initiated. -The device was not switched off.	-Start therapy. -Switch off the device.

*The alarm "System closed" only occurs if it is enabled in patient mode (please refer to chapter 3.3).

Contact the simex Medizintechnik GmbH or your service partner if the malfunction cannot be corrected by the described measures.

6 Transport, Storage and Disposal

6.1 Decontamination prior to Shipment

Prior to passing on the **simex *cuff M* or simex *cuff S*** to other, new users, the devices must be properly processed by simex Medizintechnik GmbH or by a simex Medizintechnik GmbH professional to protect subsequent users. Processing is mandatory in accordance with the German Medical Device Operator Ordinance (MPBetreibV), German Medical Devices Act (MPG) and the manufacturer's instructions.

simex Medizintechnik GmbH offers its partners and customers fast and proper processing as well as required testing services (please refer to chapter 4).

The **simex *cuff M* and simex *cuff S*** devices must be cleaned and disinfected prior to shipment to simex Medizintechnik GmbH. Please follow the instructions in chapter 4.1.2! Please affix the supplied "Used Medical Device" label to the shipping carton! Please give simex Medizintechnik GmbH advance notice of your product return. The product return form is provided on our internet page at www.simexmed.de.

6.2 Storage

Store the **simex *cuff M* and simex *cuff S*** devices as indicated in the Technical Data (chapter 7)!

The battery of the **simex *cuff M* or simex *cuff S*** subglottic aspiration device must be charged prior to storage of the device. This ensures that the device is operational at all times.
Fully recharge the battery if the **simex *cuff M* or simex *cuff S*** device is not used for a longer period of time (approx. 10 months).

6.3 Disposal

- The components of the device must be disposed of in a proper manner at the end of the product's service life.
- Ensure that the disposed components are clean and carefully sorted by material.
- The housing material has a material symbol mark and is fully recyclable.
- Decontaminate the device and the accessories prior to disposal.
- According to EU Directives 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) and 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II), the device must not be disposed of in domestic waste.
- The device and accessories may be disposed of via simex Medizintechnik GmbH or the service partner.
- Outside of the EU: Follow the disposal requirements of your country!

7 Technical Data

7.1 simex *cuff M*

Flow rate	max. 8 l/min (low flow)
Pressure	-60 mbar to -300 mbar (in steps of 10 mbar) (medium vacuum) Conversion factor: 10 mbar ~ 1 kPa ~ 7.5 mmHg
Canister	Disposable secretion canister (250 ml)
Suction tube	PVCnoDEHP - suction tube with Luer connector, Ø 4 mm (internal), length 150 cm
Power supply unit	FRIWO FW 7555M/12, cable length 4 m
Nominal voltage of the power supply unit	In: AC 100 – 240 V~ / 50-60 Hz / 350 – 150 mA In (UL only): 120 Vac / max. 350 mA / 50-60 Hz Out: DC 12 V / 1,25 A
Maximum load current	1.25 A
Nominal voltage of the circuit board	12 V
Power consumption at 12 V	15 W
Permissable input current at 12 V	1.25 A
Protection class as per IEC 60601-1	Type BF
Risk classification as per 93/42/EEC, IX	IIa
Protection class as per IEC 60601-1	II
Degree of protection (IP code) as per IEC 60529	IP22
CE marking	CE0843
UL marking	AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008)
Sound emission	Operation: 35 dB (A) High priority alarm: 52 dB (A) Low priority alarm: 49 dB (A)
Ambient conditions	Transport/Storage: -25°C to +60°C humidity of max. 93% non-condensing
	Operation: +5°C to +40°C humidity 15% to 93% non-condensing
	Air Pressure: 825 hPa to 1060 hPa
Battery, rechargeable	7.4 V, 4.4 Ah – Lithium ions
Charging time if battery is empty Charging time if battery is approx. 50% full	6 - 7 hours 3 - 3.5 hours
Dimensions (H x W x D) in mm	165 x 220 x 90
Weight (base unit)	1.2 kg
Pressure measurement accuracy	Target pressure > -120 mbar max. Δ 5 % Target pressure < -120 mbar max. Δ 10 %
Operating mode	Intermittent suction
Operating time	Continuous operation
Battery-powered runtime	Approx. 18 hours when the vacuum pump is at full capacity
Item number	100678-3

7.2 simex *cuff S*

Flow rate	max. 8 l/min (low flow)	
Pressure	-60 mbar to -300 mbar (in steps of 10 mbar) (medium vacuum) Conversion factor: 10 mbar ~ 1 kPa ~ 7.5 mmHg	
Canister	Disposable secretion canister system (1,000 ml)	
Suction tube	Disposable suction tube, length 180 cm, sterile (REF: 112203)	
Power supply unit	FRIWO FW 7555M/12, cable length 4 m	
Nominal voltage of the power supply unit	In: AC 100 – 240 V~ / 50-60 Hz / 350 – 150 mA In (UL only): 120 Vac / max. 350 mA / 50-60 Hz Out: DC 12 V / 1,25 A	
Maximum load current	1.25 A	
Nominal voltage of the circuit board	12 V	
Power consumption at 12 V	15 W	
Permissable input current at 12 V	1.25 A	
Protection class as per IEC 60601-1	Type BF	
Risk classification as per 93/42/EEC, IX	IIa	
Protection class as per IEC 60601-1	II	
Degree of protection (IP code) as per IEC 60529	IP22	
CE marking	CE0843	
UL marking	AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008)	
Sound emission	Operation:	35 dB (A)
	High priority alarm:	53 dB (A)
	Low priority alarm:	51 dB (A)
Ambient conditions	Transport/Storage:	-25°C to +60°C humidity of max. 93% non-condensing
	Operation:	+5°C to +40°C humidity 15% to 93% non-condensing
	Air Pressure:	825 hPa to 1060 hPa
Battery, rechargeable	7.4 V, 4.4 Ah – Lithium ions	
Charging time if battery is empty Charging time if battery is approx. 50% full	6 - 7 hours 3 - 3.5 hours	
Dimensions (H x W x D) in mm	290 x 259 + 100 (canister) x 130	
Weight (base unit)	2.2 kg	
Pressure measurement accuracy	Target pressure > -120 mbar Target pressure < -120 mbar	max. Δ 5% max. Δ 10%
Operating mode	Intermittent suction	
Operating time	Continuous operation	
Battery-powered runtime	Approx. 18 hours when the vacuum pump is at full capacity	
Item number	100679-3	

7.3 EMC Information

 **ATTENTION!**	Medical electrical equipment is subject to special precautionary measures regarding electromagnetic compatibility and must be installed and operated in accordance with the EMC information provided in the accompanying documentation!
 **ATTENTION!**	Portable and mobile RF communication equipment can affect medical electrical equipment!
 **CAUTION!**	The use of accessories and spare parts (incl. transformers and cables) not recommended by simex Medizintechnik GmbH may increase the emission of electromagnetic interference or reduce the electromagnetic immunity of the devices. Damage caused by using non-recommended accessories and spare parts or by improper use is not covered by warranty in any case. Only use original simex accessories and spare parts!
 **CAUTION!**	Use of the recommended accessories and spare parts (incl. transformers and cables) in devices other than the **simex *cuff M* and simex *cuff S*** may increase the emission of electromagnetic interference or reduce the electromagnetic immunity. Damage caused by using recommended accessories and spare parts in other devices or by improper use is not covered by warranty in any case. Use the accessories and spare parts only with the **simex *cuff M* and simex *cuff S*** devices**.**
 **WARNING!**	The **simex *cuff M* and simex *cuff S*** must not be used directly adjacent to or stacked with other devices. If operation adjacent to or stacked with other devices is necessary, monitor the **simex *cuff M* and simex *cuff S*** devices in this configuration to verify proper operation!

The **simex *cuff M* and simex *cuff S*** devices meet the requirements of IEC 60601-1-2/EN 60601-1-2 "Electromagnetic Compatibility – Medical Electrical Equipment". Electromagnetic interference is therefore reduced to a minimum.

Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The **simex *cuff M* and simex *cuff S*** devices are intended for operation in the electromagnetic environment specified below. The customer or the user of the **simex *cuff M* or simex *cuff S*** must ensure that it is operated in such an environment.		
Emissions measurement	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The **simex *cuff M* and simex *cuff S*** devices use RF energy for their internal function only. Their RF emissions are therefore very low and not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **simex *cuff M* and simex *cuff S*** devices are appropriate for use in all facilities incl. private residences and those directly connected to the public power supply network that supplies buildings used for residential purposes.
Harmonic emissions pursuant to IEC 61000-3-2	Nonapplicable	
Voltage fluctuations / Flicker emissions pursuant to IEC 61000-3-3	Nonapplicable	

Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The **simex *cuff M* and simex *cuff S*** devices are intended for operation in the electromagnetic environment specified below. The customer or user of the **simex *cuff M* or simex *cuff S*** must ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) pursuant to IEC 61000-4-2	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances / bursts pursuant to IEC 61000-4-4	±2kV for power supply lines ±1kV for input and output lines	±2kV for power supply lines ±1kV for input and output lines	Main supply voltage should be of the same quality as in a typical commercial, living or hospital environment.
Interference voltages / Surges pursuant to IEC 61000-4-5	±1kV voltage differential mode ±2kV common mode	±1kV voltage differential mode ±2kV common mode	Main supply voltage should be of the same quality as in a typical commercial, living or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines pursuant to IEC 61000-4-11	<5% U_T (>95% dip of U_T) for ½ period 40% U_T (60% dip of U_T) for 5 periods 70% U_T (30% dip of U_T) for 25 periods <5% U_T (>95% dip of U_T) for 5s	<5% U_T (>95% dip of U_T) for ½ period 40% U_T (60% dip of U_T) for 5 periods 70% U_T (30% dip of U_T) for 25 periods <5% U_T (>95% dip of U_T) for 5s	Main supply voltage should be of the same quality as in a typical commercial, living or hospital environment. If the user of the **simex *cuff M* or simex *cuff S*** requires continued operation during mains power outages, it is recommended to power the device from an uninterruptible power supply or a battery.
Magnetic fields at power frequency (50/60 Hz) pursuant to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic for a typical location in a typical commercial, living or hospital environment.
Note: U_T is the AC mains voltage prior to the application of the test levels.			

Table 3

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The **simex *cuff M* and simex *cuff S*** devices are intended for operation in the electromagnetic environment specified below. The customer or user of the **simex *cuff M* or simex *cuff S*** must ensure that it is used in such an environment.			
Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Conducted RF disturbances pursuant to IEC 61000-4-6 Radiated RF disturbances pursuant to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **simex *cuff M* and simex *cuff S***, incl. cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d= 1.2 √P d= 1.2 √P for 80 MHz to 800 MHz d= 2.3 √P for 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be lower than the compliance level in each frequency range.[b] Interference is possible in the vicinity of devices bearing the symbol shown below. 
NOTE 1:	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with respect to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **simex *cuff M* and simex *cuff S*** devices are used exceeds the applicable RF compliance level above, the device should be monitored to verify proper operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] The field strength should be lower than 3 V/m for the 150 kHz to 80 MHz frequency range.

Table 4

Recommended protection ratio between portable and mobile RF communications equipment and the **simex *cuff M* and simex *cuff S***.			
The **simex *cuff M* and simex *cuff S*** devices are intended for operation in an electromagnetic environment in which the radiated RF disturbances are controlled. The customer or the user of the **simex *cuff M* or simex *cuff S*** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **simex *cuff M* or simex *cuff S*** as recommended below, according to the maximum output of the communications equipment.			
Rated maximum output power of transmitter (W)	Protection ratio based on the frequency of the transmitter (m)		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended protection ratio in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

8 Ordering Information

8.1 simex *cuff M*

Item number	Description	PU
100442	Power supply unit FRIWO FW 7555M/12 (incl. all country adapters)	1
100489	Disposable secretion canister (250 ml) with Luer connector	1
100348	IV pole / rail holder *cuff M*	1
100500	Carrying bag for cuff M, single use	1
112201	Disposable suction tube, 50cm, Luer (sterile)	1

8.2 simex *cuff S*

Item number	Description	PU
100442	Power supply unit FRIWO FW 7555M/12 (incl. all country adapters)	1
100414	External canister	1
100509	Disposable liner (1,000ml)	1
100416	Holder for external canister	1
100012	Double filter system replacement set (DFS®)	1
20103	Connecting tube	1
100484	Universal bed holder	1
100346	Variable IV pole /rail holder systems *cuff S*	1
100501	Carrying bag for *cuff S*, single use	1
112203	Disposable suction tube (sterile)	1

9 Publishing Information

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