Operating Manual

SIMEX Medizintechnik GmbH

cuff S

SIMEX Subglottic Aspiration System

Caution:
Federal law restricts this device to sale or rental by or on the order of a physician.

The safety of the **SIMEX *cuff S*** is in accordance with the generally accepted technical rules and standards and the guidelines of the **Medical Devices Directive.**

The **SIMEX *cuff S*** is labelled with the **CE mark CE0483** pursuant to the EU Directive of the Council for Medical Devices 93/42/EEC and meets the essential requirements of Annex I of this directive.
The **SIMEX *cuff S*** is IEC 62353 tested.
The quality management system used at SIMEX Medizintechnik GmbH is certified according to the relevant international quality management standards.
The **SIMEX *cuff S*** is a medical aspirator device and was assigned to class IIa pursuant to the EC Directive 93/42/EEC, Annex IX.

Errors and omissions excepted.

SX4000OMrev06=140915

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1 Information for the user

1.1 Using this instruction manual

Please read this instruction manual completely before using the **SIMEX *cuff S*** device for the first time.

Read the safety information (Chapter 1.6) to avoid hazardous situations.

This instruction manual is an integral component of the **SIMEX *cuff S*.** Therefore, please keep this instruction manual in an easily accessible location.

Include this instruction manual if you pass on the **SIMEX *cuff S*** to third parties.

1.2 Graphic symbols

1.2.1 Device and packing

Illustration	Meaning
	**Caution:** Federal law restricts this device to sale or rental by or on the order of a physician
	Warning or safety precaution information follows.
	**NOTE** Note containing useful information and tips.
	Attention: observe the instruction manual“, according to DIN EN 980
	Protection class: **Type BF** (Body Floating)
	Temperature limit
	Do not dispose of this device together with the household waste.
	Unsterile

Illustration	Meaning
	Fuse
REF	Order number
SN	Serial number
LOT	Batch number
	Manufacturing date
	Manufacturer
	Do not use if the packaging is damaged!
	Not intended for re-use
	Store in a dry place
MR	MRI - Unsafe
	Protection Class II

1.2.2 Display

Illustration	Meaning
	Battery fully charged
	Low battery
	Battery fully discharged
	Up
	Down
	Run time
	Pause time
OK	Ok (Enter, On)
C	Cancel (Off)
	Power supply is connected
	Filter lifetime reached; exchanging the DFS® through service is mandatory!
	Radiofrequency - RF
	Key Lock

1.3 Symbol convention

Illustration	Meaning
•	Itemisation
1.	Carry out the actions in the
2.	described order!

1.4 Glossary

A

Aspirated material

Aspirated material is a generic term for secretions, bodily fluids as well as rinsing fluids that typically accumulate in connection with the aspiration of the upper airways. These can be aspirated with the device.

C

Contamination

Contamination means that bacteria and viruses from the aspirated material have come into contact with the device.

D

DFS® Double filter system

An external filter in the disposable liner combined with a bacteria filter integrated in the aspiration device form the double filter system. The double filter system effectively protects the interior of the device against contamination and over-aspiration. It allows the safe conditioning as well as the rapid re-use of the product.

M

Maintenance

Maintenance is required for every new patient. Maintenance means that any parts which come or may come into contact with the aspirated material are replaced.The maintenance may only be performed by SIMEX Medizintechnik GmbH or by service partners authorised by SIMEX Medizintechnik GmbH.

O

Over-aspiration

If the disposable liner is full and not exchanged before the next aspiration, this may result in over-aspiration. Over-aspiration means that the aspirated material cannot be absorbed in the disposable liner and the aspirated material is therefore aspirated into the interior of the device. This may cause contamination of the interior of the device.

1.5 Indications for Use

The SIMEX Subglottic Aspiration System is indicated for vacuum suction, extraction, aspiration and removal of surgical fluids, tissue (including bone), bodily fluids or infectious materials from wounds or from patient´s airway or respiratory system, either during surgery 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.

Contraindications

The SIMEX Subglottic Aspiration System is not intended for continuous operation in low vacuum drainage (e.g. thoracic drainage).

Warnings and Precautions

Never use the SIMEX Subglottic Aspiration System simultaneously on more than one patient!
Do not use for aspiration of flammable, corrosive or explosive liquids and gases!

Special Note

The SIMEX **cuff S** is used in conjunction with cuffed endotracheal (ETT) or Tracheal (TT) tubes that have specialized suction cannula/lumen designed for the suctioning of subglottic secretions.
The SIMEX **cuff S** connects to the suction lumen of the ETT or TT tubes using the sterile suction tubing provided as an accessory to intermittently aspirate the subglottic secretion accumulated above the ballooned cuff of these ETT or TT tubes.

CAUTION!

To prevent the possibility of misconnections, always trace the tubing to the point of origin before connecting to a device or port. Re-check connections and trace all patient tubes and catheters, including the suction tubing to their source upon a patient's arrival to a new setting or service.

1.6 Basic safety information

CAUTION!

Damage to health when handling infectious germs or pathogens.
Infectious germs and pathogens of the aspirated material cause damage to the health.

Observe the hygiene, cleaning and decontamination information (chapter 4.1).

CAUTION!

- Always use an Endotracheal (ETT) or Tracheal (TT) cuffed tubes with specialized suction lumen for the aspiration. The aspiration hose may never come into direct contact with the aspiration site.
- Follow the maximum pressure setting recommended by the manufacturer of the endotracheal (ETT) or tracheal (TT) tube with integrated suction lumen.

CAUTION!

The **SIMEX cuff S** is a medical device that requires special safety measures in regard to EMC. It must be installed and put into operation in accordance with the EMC information in Section 7.1.

WARNING!

Warning about damages due to incorrect supply voltage.
Improper operation causes overvoltage in the device which may be passed on to the user.

- Before starting the device, make sure that the mains power supply is designed for a voltage of 100-240 V AC.
- Make sure that a voltage of 12 V is available for mobile, battery-supplied operation.

CAUTION!

Hazard to persons if used incorrectly.

- Only use the device for the intended use.
- Never use the device for permanent operation in low vacuum drainages (e.g. thoracic drainage).

ATTENTION!

Damage to the device if operated incorrectly.

- Never aspirate flammable, corrosive, or explosive fluids or gases!

CAUTION!

Safety defects due to incorrect accessories and spare parts.
The use of accessories and replaceable parts not recommended by SIMEX Medizintechnik GmbH as it may impair the safety and function of the device. See Section 8 for a list of replacement parts and accessories. All service and repair must be carried out by SIMEX Medizintechnik GmbH or its authorized representatives. Use of spare parts, or repair not authorized by SIMEX may impair the safety and function of the device and will void the Warranty.

- Exclusively use original accessories and spare parts recommended by SIMEX Medizintechnik GmbH.

ATTENTION!

Damage of the device caused by fluids seeping in.

- Do not use the device in the presence of swell water.
- Do not use the device in damp rooms or when taking a bath or shower.
- Avoid getting the power supply, plug and display foil wet.
- Never immerse the device into water or other fluids (including when it is not in operation).

ATTENTION!

Damage to the device caused by heat.

- Never cover the power supply.
- Keep the aspiration device as well as the power cable and the power supply away from other heat sources.

1.7 User requirements

WARNING:
The **SIMEX *cuff S*** device may only be operated and used by trained personnel. Before using the device, familiarise yourself with the working mode of the **SIMEX *cuff S***

1.8 Information on product liability

The liability for the function of the device is transferred to the operator if:
- the **SIMEX *cuff S*** device is used for other than the intended use,
- the **SIMEX *cuff S*** is not used in accordance with the instruction manual,
- the **SIMEX *cuff S*** is opened by unauthorised persons,
- installation, settings, upgrades, maintenance or repairs are carried out by unauthorised persons
- no original accessories and spare parts are used.

1.9 Compatibility of the materials

ATTENTION!

Aggressive substances can damage the device and the accessories.
- Observe the information on cleaning (Chapter 4.1)

2 Product description

2.1 Overview illustration

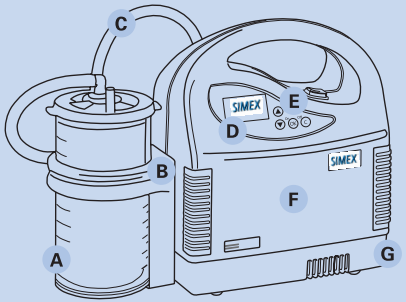


Fig.1

A Disposable secretion container system "Liner"

B Holder for external container"Liner"

C Connecting hose
D Display
E Control panel
F **SIMEX *cuff S***
G Connector for power supply

2.2 Scope of delivery

- **SIMEX *cuff S***
- Disposable secretion container system (consisting of "Liner" and rigid external container)
- Holder for external rigid container
- Connecting hose
- Disposable suction tubing (in sterile package)
- Power supply (type: FW 7555M/12) incl. country-specific adapter
- Instruction manual

2.3 Product features

CAUTION!

Hazard to persons if used incorrectly.
- Only use the device for the intended use.
- Never use the device for permanent operation in low vacuum drainages (e.g. thoracic drainage).

ATTENTION!

Damage to the device if operated incorrectly.
- Never aspirate flammable, corrosive, explosive fluids or gases!

The **SIMEX *cuff S*** is designed for in-patient and mobile use for medical, subglottic aspirations of secretions accumulated in the subglottic space above the cuffed tracheal or endotracheal tubes. It is intended for moderate vacuum aspiration and can be used in the clinical setting and in the practice, during the transport to the hospital as well as in a private setting.

The **SIMEX *cuff S*** is a light-weight portable battery-operated device. The **SIMEX *cuff S*** is powered by the integrated battery or the included power supply which is also used to charge the battery.

The vacuum is generated by a maintenance-free membrane pump powered by an electric motor. After switching it on, the vacuum pump creates a vacuum in the hose conduction system and the disposable secretion container system. This vacuum is used to aspirate the secretions (via an ETT or TT cuffed tube with specialized suction lumen). The secretion is removed away from the patient and collected in the disposable liner. If the disposable liner is full, an integrated bacterial filter stops the secretion material from flowing in.

The **SIMEX *cuff S*** may only be operated with the supplied disposable secretion container system.

2.3.1 Disposable secretion container system

The disposable secretion container system consists of the external rigid container and the "Single Patient Use" disposable liner. A bacteria filter and gelling agent are integrated in the disposable liner. The hydrophobic bacteria filter integrated in the disposable liner is 99.999% effective against bacteria and viruses. If the user makes an error, this integrated filter prevents over-aspiration. If the fluid reaches the filter, aspiration is no longer possible and the display shows the error message "System closed" and the aspiration process is interrupted.

In addition, the SIMEX double filter system DFS® protects the **SIMEX *cuff S*** from over-aspiration and contamination.
If over-aspiration occurs nevertheless, the **SIMEX *cuff S*** requires professional maintenance by SIMEX Medizintechnik GmbH or a service partner authorised by SIMEX Medizintechnik GmbH.

Gelling agent:
"OneWay" disposable liner filled with aspirated material can be transported and disposed of without leaking by means of the gelling agent. Irrespective of the aspiration intervals, the aspirated fluid is gelled solid after an average gel time of 2-5 minutes.

The disposable "liner"and sterile suction tubing are intended for one-time use. Discard and replace the disposable "liner" if it is full, or weekly, and each time for a new patient.

2.3.2 Battery

Battery charging information

The battery charge level is indicated on the display.

Before the first use of the **SIMEX *cuff S***, it is urgently recommended to charge the battery completely.

The **SIMEX *cuff S*** is equipped with a lithium-ion battery, for which the self discharge is low compared to conventional battery types.

Store and charge the **SIMEX *cuff S*** device in compliance with the ambient conditions stated in the technical specifications, optimally at room temperature. Never store the device with the battery discharged! If the device is not used for a prolonged period of time (approx. 10 months), the battery must be fully recharged.

Lithium-ion batteries do not have a memory effect. After the initial charge, they can and should therefore be recharged any time. But frequent short charging should be avoided.

The battery of the **SIMEX *cuff S*** is protected against deep discharge by means of safeguards; but the charging information above should nevertheless be observed. In addition, the battery is protected against overheating while being charged. If the battery temperature is exceeded during the charging process because of inadequate ambient conditions, the charging process will be temporarily interrupted to cool off the battery. This is for the safety and protection of the battery.

2.3.3 Pressure settings

As soon as the **SIMEX *cuff S*** is switched on, the pressure settings can be adjusted individually by medical professionals.
The pressure can be set in the range of -20 to -300 mbar (in 10 mbar increments). The default pressure setting is -100 mbar. The recommended guidelines for pressure ranges for adults is -106 to -200 mbar or -80 to -150 mmHg. The pressure setting in children is not known, but should not exceed -106 mbar or -80 mmHg.

CAUTION: Maximum pressure must not exceed -200 mbar or -150 mmHg.

The lowest possible pressure setting should always be used. Start with lowest pressure and increase as needed according to physician instructions. Any settings on the device must be carried out at the instruction of and only by medical professionals. Press the Keylock function to lock in the set pressure.
Before switching on the **SIMEX *cuff S*** please make sure that the device is equipped with a disposable secretion container system.

CAUTION: In case of blockage of secretion fluid in the suction lumen of ETT or TT cuffed tubes, the medical professional may increase the pressure setting from between -200 up to -300 mbar to clear the blockage and then return back to the recommended lower pressre settings.

2.3.4 Information on the double filter system

CAUTION!

Damage to health when handling infectious germs or pathogens.
Infectious germs and pathogens of the aspirated material cause damage to the health.

- Make sure that the disposable liner is replaced on time or when full.
- Always have at least one replacement disposable liner ready for use.

The SIMEX double filter system DFS® consists of the bacteria filter integrated in the disposable liner and the internal filter integrated in the device. Both filters are hydrophobic (fluid-repelling) bacteria filters with a 99.999 % efficiency against bacteria and viruses.

The SIMEX double filter system DFS® effectively protects against over-aspiration and contamination. It allows fast, simple and cost-efficient maintenance.

The disposable liner is intended for one-time use. Replace the disposable liner when it is full or weekly and before every new patient.

When replacing the disposable liner, please refer to the enclosed instruction manual!

Similar to the disposable liner, the internal filter system is not intended for re-use. To ensure consistent functional characteristics, the internal filter system must be replaced in case of over-aspiration for every new patient or for maintenance/repair. In case of over-aspiration of the internal filter, it must be replaced by SIMEX Medizintechnik GmbH or by a service partner authorised by SIMEX Medizintechnik GmbH.

2.4 Warranty

The warranty period for devices supplied by SIMEX Medizintechnik GmbH is 2 years. It is neither extended nor renewed as a result of work performed under the warranty.
The warranty period for the battery is 6 months.
Wear parts are excluded from the warranty.

SIMEX Medizintechnik GmbH is only responsible for effects on the safety, reliability and specific performance if:

- Maintenance and repair work has been carried out by specialist personnel authorised by SIMEX Medizintechnik GmbH, or by SIMEX Medizintechnik GmbH itself.
- The concerned product has been used and operated in accordance with the instruction manual and has not been used for any unintended purposes.

All warranty entitlements become void if the device is opened by unauthorised persons, the safety seal is removed/damaged or repairs are carried out by unauthorised persons.

3 Operation

CAUTION!

Hazard to persons if used incorrectly.

- Read Sections 3.1 and 3.2 prior to use.
- Only perform the aspiration in the subglottic space or respiratory tract after being instructed by qualified medical personnel.
- Use only ETT or TT cuffed SSD tubes with special suction lumen that are indicated for aspiration of subglottic secretions!

WARNING!

Loss of function caused by aspirated material.

- Make sure that the disposable liner is replaced on time or as needed. If the disposable liner is full, the integrated bacterial filter will be compromised. This interrupts the aspiration process.
- Switch off the device when replacing the disposable liner .
- In case of over-aspiration of the device, it must be properly maintained by SIMEX Medizintechnik GmbH or by a service partner authorised by SIMEX Medizintechnik GmbH.

3.1 Installation and operation

3.1.1 Operation

Please read the safety information in Chapter 1.6 before starting the device for the first time. Always have an additional Single Patient Use disposable liner ready because this is essential for safe operation!

Unpack the device and the accessories. Inspect all accessories contained in the scope of delivery before every use of the **SIMEX *cuff S***. It is essential to avoid kinking when connecting the hoses. Check that the disposable secretion container system is correctly attached before switching the device on. Fully charge the battery before using the device for the first time.

3.1.2 Connecting the SIMEX *cuff S*

Use the power supply of the **SIMEX *cuff S*** (Chapter 2.1, Fig.1 (G)), to connect the device to the power grid by means of the included power supply (type: FW7555M/12) if necessary for charging or operating the device. Only use the included power supply.

3.1.3 Positioning the SIMEX *cuff S*

The **SIMEX *cuff S*** can be positioned at the patient's bed. (Optional) - a trolley, a holder for standard guide rails or a holder for the bed are available.
With the use of shoulder bag **SIMEX *cuff S*** is also suitable for mobile use. It is at the clinician's discretion to decide whether the patient's condition permits portable operation.

3.1.4 Connecting the SIMEX disposable secretion container system (Liner and rigid container)

CAUTION!

Loss of function caused by the collapse of the disposable liner. A leak on the cover may cause air to flow into the external rigid container. This may cause the disposable liner to collapse.

- When using the disposable secretion container system , make sure that the cover of the disposable liner is firmly connected with the external rigid container.
- Make sure that all connections are tight.
- Observe the manufacturer's instructions!

The original SIMEX disposable secretion container system consists of the external rigid container, the holder for the external rigid container, the single patient use disposable liner and the connecting hoses.

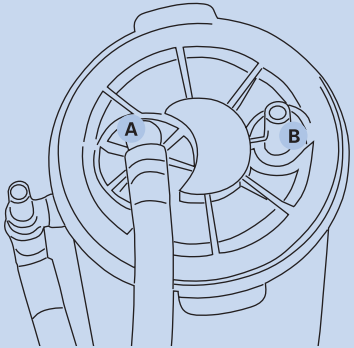


Fig. 2

A Vacuum connection
B Patient connection

Please observe the instruction manual enclosed, for the disposable secretion container system ("Liner" and "rigid container").

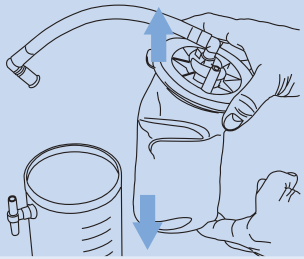


Fig. 3

1. Unpack the Single Patient Use disposable "Liner" and expand it completely.

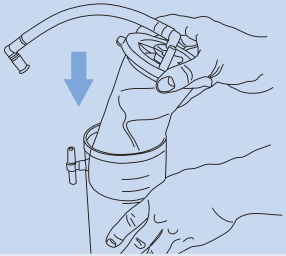


Fig. 4

2. Place the Single Patient Use disposable "Liner" into the external rigid container. Firmly push the cover of the "Liner" down along the edges to ensure a tight seal between the liner and the rigid container.

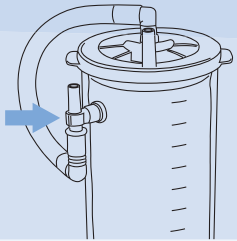


Fig. 5

3. Attach the pre-mounted connecting hose "**A**"of the disposable "Liner" to the bottom end of the T-valve of the external rigid container as shown in Fig. 5
4. Connect the vacuum connection (spout) of the device to the corresponding vacuum connection of the external rigid container (top end of the T-valve). Use the supplied connecting hose for this purpose.
5. Connect the supplied sterile suction tubing (supplied as an accessory) to the patient connection of the "Liner" (see Fig. 2 B).

3.1.5 Connecting to ETT or TT cuffed tube with special Suction Lumen

Connect the disposable secretion canister "liner" to the suction lumen of the ETT or TT cuffed tube by connecting the sterile suction tubing provided as an accessory to the patient connection of the canister liner

Caution:
The suction/aspiration tubing must never come in direct contact with the aspiration site. Tubing connections should be made by trained clinical staff only.

Caution:

The ETT or TT cuffed tubes with special suction lumen are off the shelf sterile devices used for aspiration of subglottic secretions. These devices are marketed by a number of manufactures and are indicated for aspiration of subglottic secretion from the subglottic space. The suction lumen port of all of these devices can easily connect to the disposable sterile suction tubing of the SIMEX **cuff S** pump. It is entirely up to the physician to decide which brand ETT or TT cuffed tube is suitable for the patient!

3.2 Operating the SIMEX *cuff S*

1. Push the button (OK) for 1-2 seconds to switch on the **SIMEX *cuff S***. The following start screen is displayed:

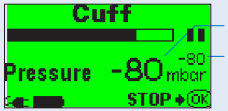
(yellow)

2. The following display will appear after five seconds:
(Default target value: -100 mbar)

Aspiration time
Target value
Pause time (yellow)

3. Set the specified pressure value (target value) by means of the arrow keys (▲) (▼).

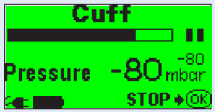
4. Start the pump by pushing the (OK) button. Two values are shown on the display.



Current value
Target value
(green)

The bar on the top of the image fills in from left to right, illustrating the aspiration time.

The aspiration time is followed by the pause time.



(green)

The bar on the top of the image empties from right to left, illustrating the pause time.

5. To stop the pump, push the OK button.

6. To switch off the **SIMEX *cuff S*** push the C button for 3 seconds.

3.2.1 Setting the aspiration and pause times

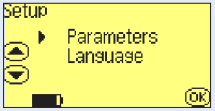
When starting the **SIMEX *cuff S***, it is possible to set the aspiration and pause times. The **SIMEX *cuff S*** will remember these settings for subsequent starts. To set the times, proceed as follows:

1. Push the OK button for 1-2 seconds to switch on the **SIMEX *cuff S***. The following start screen is displayed:

(yellow)

2. Press the arrow keys ▲ ▼ while the start screen is displayed. The *Setup* menu is displayed.

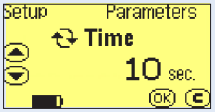
3. Use the arrow keys ▲ ▼ to select the *Parameters* menu.



(yellow)

4. Confirm your selection with the OK button.

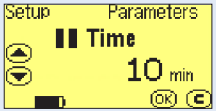
5. Use the arrow keys ▲ ▼ to set the specified aspiration time [seconds]. The aspiration time can range from a minimum of one second to a maximum of 60 seconds (in 1 second increments).



(yellow)

6. Confirm your selection with the OK button.

7. Use the arrow keys ▲ ▼ to set the specified pause time [seconds]. The pause time can range from a minimum of one minute to a maximum of 60 minutes (in 1 minute increments).



(yellow)

8. Confirm your selection with the OK button.

3.2.2 Language selection

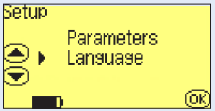
When starting the **SIMEX *cuff S***, it is possible to select a language. The **SIMEX *cuff S*** will remember this language selection for subsequent starts. To select the language, proceed as follows:

1. Push the OK button for 1-2 seconds to switch on the **SIMEX *cuff S*.** The following start screen is displayed:

(yellow)

2. Press the arrow keys ▲ ▼ while the start screen is displayed. The *Setup* menu is displayed.

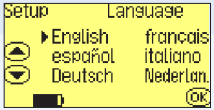
3. Use the arrow keys ▲ ▼ to select the *Language* menu.



(yellow)

4. Confirm your selection with the OK button.

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



(yellow)

6. Confirm your selection with the OK button.

3.3 Patient mode

When starting the **SIMEX *cuff S*,** it is possible to select the patient mode. The patient operating time can be viewed and reset in patient mode. To select the patient mode, proceed as follows:

1. Push the ⓞⓚ button for 1-2 seconds to switch on the **SIMEX *cuff S***. The following start screen is displayed:

(yellow)

2. Press the ⓒ button during the start screen, keep holding it down and press the ⓞⓚ button (for 1-2 seconds). An authorisation screen is displayed.

(blue)

3. Use the arrow keys ▲ ▼ to enter code ”1000“. Press the arrow key ▲ once and confirm the entry with the ⓞⓚ. button. Confirm the other digits of the code with the ⓞⓚ button.

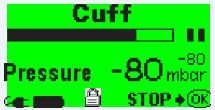
4. The patient operating time is displayed after the authorisation is complete.

(blue)

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

6. Exit the patient mode by pushing the OK button.

3.4 Key Lock



The “Key Lock” feature is automatically activated in 15 minutes of operating. The “Key Lock” can be manually deactivated by simultaneously pressing the up and down arrow keys together. (green)

4 Maintenance

4.1 Cleaning and care

4.1.1 General information

CAUTION!

Damage to health when handling infectious germs or pathogens.

Infectious germs and pathogens of the aspirated material cause damage to health.

- Wear suitable disposable gloves to exchange the disposable liner.
- Use the disposable "liner" for one patient only.
- Replace the disposable liner when it is full or weekly and for every new patient.
- (a)-Wipe clean and disinfect all parts of the pump that have come into contact with the aspirated material.
  (b)- Discard and dispose all disposable parts and accessories that are considered "not reusable" or "single use only" (i.e., disposable "liner", PVC tubing)

CAUTION!

Health hazards associated with the handling of disinfectants.

- The use of suitable disposable gloves is recommended for the disinfection.
- Please observe the instructions from the disinfectant manufacturer.

ATTENTION!

Damage to the device caused by the use of improper cleaning agents.

- Do not use disinfectants containing acetone. They can cause damage or a visual impact of parts of the case/housing.
- Please observe the instructions for use from the disinfectant manufacturers, especially regarding the compatibility with materials and surfaces as well as information about the concentration.
- SIMEX Medizintechnik GmbH recommends Incidin PLUS, TERRALIN for the disinfection by wiping.

4.1.2 Cleaning / disinfection of device surface

Clean regularly and disinfect the surface of the device at least once a week. All devices can be wiped with a moist, lint-free cloth. Please refer to the previous Chapter 4.1.1 for information about disinfection by wiping.

After prolonged use, minor discolorations of the plastic parts of the case/housing may occur. However, they do not impair the functionality of the device.

If the inside of the device comes into direct contact with fluids, the device must be checked by SIMEX Medizintechnik GmbH or an authorised service partner of SIMEX Medizintechnik GmbH.

4.1.3 Cleaning and disinfection of the external rigid container

1. Rinse the external rigid container under running water.
2. Immerse the external rigid container into the disinfection solution by observing the specific concentration volume. Alternatively, the external rigid container can be autoclaved at 121 °C for 20 minutes.
3. Then thoroughly rinse the external rigid container and let it dry.

SIMEX Medizintechnik GmbH recommends replacing the external rigid container at least every **four weeks** and for every new patient.

4.1.4 PVC suction tube and other hoses

1. When the disposable canister "Liner" is full, it must be replaced with a new Liner.
2. Dispose of all hoses intended for one-time use! This includes PVC suction tube.
3. When the external rigid container is being cleaned and disinfected, all tubing and hose connections must be removed and discarded.

4.1.5 "Single Patient Use" disposable liner

Properly dispose of the disposable liner (see Chapter 6.3). It is designed for one-time use **Only.**

4.2 Maintenance and service

- If used in compliance with the instruction manual, the **SIMEX *cuff S*** is maintenance-free.
- Conduct a visual inspection before each use. This should also include the accessories.
- The device may only be opened and repaired by SIMEX Medizintechnik GmbH or qualified persons authorised by SIMEX Medizintechnik GmbH by observing the service documents described by the manufacturer as well as the technical and hygienic safety procedures.
- For repairs, the device can be returned to SIMEX Medizintechnik GmbH directly or via the dealer from whom you purchased the device.
- Before returning the device for repair, all accessories such as power adaptor must be cleaned and disinfected. The device itself must be treated and wiped clean with a surface disinfectant.
- SIMEX Medizintechnik GmbH neither guarantees the error-free function of the **SIMEX *cuff S*** aspiration device nor does SIMEX Medizintechnik GmbH accept any liability for damages to property or personal injuries, if
  - no original SIMEX accessories or spare parts are used,
  - the instructions for use of this instruction manual are disregarded,
  - installation, settings, modifications, upgrades, repairs are not carried out by SIMEX Medizintechnik GmbH or persons authorised by SIMEX Medizintechnik GmbH
  - the safety seal is removed or damaged.

4.3 Inspecting the SIMEX *cuff S*

The recurring inspections shall be conducted in accordance with the respective applicable legal provisions/ directives (e.g. IEC 62353, 2007/47/EC, etc.)
We recommend conducting a safety control at least every 24 months.
It is the sole responsibility of the operator to conduct the inspections.
SIMEX Mediztechnik GmbH provides its partners and customers with the fast and professional preparation and conduct of the required inspections.

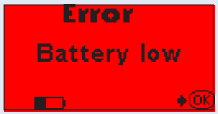
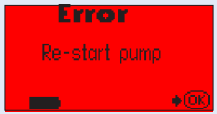
5. Troubleshooting

5.1 Error search

Error	Possible cause	Remedy
The **SIMEX *cuff S*** does not start	The battery is fully discharged	Connect to power supply
	The overflow valve is blocked (The disposable liner is full)	Replace the disposable liner
	The device is still in *Settings* mode	Complete the selection (see 3.2)
Inadequate aspiration performance	Leak in the external aspiration cycle	Check all connections for a tight fit
	The DFS® is moist	Replace the DFS® (service!)
	The battery is almost discharged	Charge the battery
No aspiration performance	The disposable liner is full	Replace the disposable liner
	The hose is not connected	Check correct hose connections
	The DFS® is moist	Replace the DFS® (service!)
	Kinked hose	Check the hose arrangement

Please contact your service partner if an error cannot be remedied with the procedures described above.

5.2 Error messages

Error message (red)	Status	Possible cause	Remedy
	Alarm on. The current operating mode continues to run in the background.	The disposable liner is full	Press ”OK“ to acknowledge the error message. Replace the disposable liner. Inspect the hose arrangement.
	Alarm on. The current operating mode continues to run in the background.	Low battery level	Press "OK" and connect to power supply.
	Alarm on. End the current operating mode.	Battery is fully discharged	Connect to power supply. Press "OK".
	Alarm on (after 15 minutes). The stand-by mode continues to run in the background.	The **SIMEX *cuff S*** pump did not start.	Press ”OK“ to acknowledge the error message. Start the pump.

Please contact your service partner if an error cannot be remedied with the procedures described above.

6 Transport, storage and disposal

6.1 Decontamination before shipping

Before passing on the **SIMEX *cuff S*** it must be maintained professionally by SIMEX Medizintechnik GmbH or qualified persons authorised by SIMEX Medizintechnik GmbH to protect the subsequent user. It is mandatory that the maintenance is performed as set forth in the Medical Devices Operator Ordinance [MPBetreibV], the Act on Medical Devices [MPG] and the manufacturer's instructions.
SIMEX Medizintechnik GmbH provides its partners and customers with the fast and professional preparation and conduct of the required inspections (see Chapter 4.3).
Before returning the device to SIMEX Medizintechnik GmbH, it must be cleaned and disinfected.
For more details, please refer to Chapter 4.1!

6.2 Storage

Store the device according to the details in the Technical Specifications (Chapter 7).
Charge the battery of the **SIMEX *cuff S*** before storing the device. This ensures operational readiness at all times.
If the **SIMEX *cuff S*** is not used for a prolonged period of time (approx. 10 months), the battery needs to be fully recharged.

6.3 Disposal

- At the end of the product life, the components of the device must be disposed of properly.
- In doing so, make sure that the device is clean and separate the materials carefully.
- The material of the housing is labelled with a symbol of the material and is completely recyclable.
- Decontaminate the device and acces-sories before disposal.
- According to the EU Directives 2002/96/EC on old electrical and electronic equipment (WEEE) and 2002/95/EC on the limitation and use of certain hazardous materials in electrical and electronic equipment (RoHS), the device may not be disposed of with the regular household waste.
- Outside of the EU: Observe the country-specific disposal provisions!

7 Technical specifications

Flow rate	max. 8 L/min
Pressure	-20 mbar to -300 mbar (in 10 mbar steps)
Container	Disposable secretion container, "liner" (1,000 ml) , "Single Patient Use Only"
Aspiration hose	Various aspiration hoses (depending on the supplier)
Rated voltage of the power supply Maximum load current Supply frequency of the power supply	100 – 240 V AC primary / 12 V DC secondary 1.25 A 50 / 60 Hz
Rated voltage of the PCB	12 V DC
Power consumption	15 W (charging and operation) / 10 W (charging only)
Current consumption	1.25 A at 12 V
Battery, rechargeable	7.4 V, 4.4 Ah – lithium-ion
Charging time when battery is discharged	6 - 7 hours
Charging time with battery 50% discharged	3 - 3.5 hours
Dimensions (H x W x D)	290 x 259 + 100 (container) x 130 mm
Weight (basic device)	Approx. 2.2 kg
Operating life	Mains: Continuous operation / battery: with maximum use of the vacuum pump: approx. 18 hours
Operating mode	Intermittent aspiration
Protection class as per IEC 60601-1	Type BF IP20
Risk class as per 93/42/EU, Annex IX	IIa
Protection class as per IEC 60601-1	II
CE marking	CE0483
Noise emission	35 dB (A)
Ambient conditions	Transport/Storage: -10°C to +60°C Operation: +5°C to +35°C Recommended charging temperature: +15°C to +30°C relative humidity: 5 to 80 %, non-condensing Air pressure: 860 hPa...1060 hPa
Item number REF	100679
UL Classification	Medical Suction Unit: WITH RESPECT TO ELECTRICAL SHOCK FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1/CAN/CSA C22.2 No. 601.13KCX)

7.1. EMC information

SIMEX *cuff S* meets the immunity to interference requirements of **IEC 60601-1-2/EN 60601-1-2 "Electromagnetic compatibility - Medical Electrical Devices"**.

This equipment has been tested and found to comply with the limits for medical electrical devices according to IEC 60601-1-2./EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

T 201

Guidelines and manufacturer `s declaration - electromagnetic emissions		
The **SIMEX *cuff S*** is intended for operation in an environment as described below. The customer or the user of the **SIMEX *cuff S*** must ensure that it is operated in such an environment.		
Emmissions Test	**Compliance**	**Electromagnetic environment - Guidance**
RF emissions as per CISPR 11	Class B	The **SIMEX *cuff S*** is suitable for use in any facilities, including domestic environments and those which are directly connected to a public supply grid which also supplies buildings used for residential purposes.
Harmonic emissions according to IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions according to IEC 61000-3-3	Not applicable	

Caution: Should a mobile phone, hand held telephone or other remote RF transmitter that exhibits the RF symbol  be activated in the proximity of the **SIMEX *cuff S***, a health care professional must immediately check and confirm the operating status of the device.

Warning: The **SIMEX *cuff S*** is intended for use by healthcare professionals only. This equipment/system may cause radio interfence or may disrupt the operating of nearby equpment . It may be necessary to take mitigation measures, such as re-orienting or relocating the **SIMEX *cuff S*** or shielding the location.

Warning: The **SIMEX *cuff S*** should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the **SIMEX *cuff S*** should be observed to verify normal operation in the configuration in which it will be used.

Warning: 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 theoreticlly with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **SIMEX *cuff S*** is used exceeds the applicable RF compliance level shown below in Table 3 (Note 1), the **SIMEX *cuff S*** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **SIMEX *cuff S.***

T 202

Guidelines and manufacturer's declaration - electromagnetic immunity			
The **SIMEX *cuff S*** is intended for operation in an ELECTROMAGNETIC ENVIRONMENT as described below. The customer or the user of the **SIMEX *cuff S*** must ensure that it is operated in such an environment.			
Immunity test	**IEC 60601 test level**	**Concordance level**	**Electromagnetic environment guidance**
Discharge of static electricity (ESD) as per IEC 61000-4-2	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	Floors should consist of wood or concrete or be covered with ceramic tiles. If the floor is covered with synthetic materials, the relative humidity must be at least 30%.
Rapid transient electrical interference variables / bursts according to IEC 61000-4-4	±2kV for power lines ±1kV for input and output lines	±2kV for power lines ±1kV for input and output lines	The supply voltage quality should correspond to that of a typical commercial or hospital environment.
Peak voltages (surges) as per IEC 6100-4-5	±1kV voltage differential mode ±2kV common mode	±1kV differential-mode voltage Not applicable	The supply voltage quality should correspond to that of a typical commercial or hospital environment.
Voltage reduction, short-term interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	<5% Ut (>95% reduction of the Ut) for ½ cycle 40% Ut (60% reduction of the Ut) 70% Ut (30% reduction of the Ut) for 25 cycles <5% Ut (>95% reduction of the Ut) for 5 sec.	<5% Ut (>95% reduction of the Ut) for ½ cycle 40% Ut (60% reduction of the Ut) for 5 cycles 70% Ut (30% reduction of the Ut) for 25 cycles <5% Ut (>95% reduction of the Ut) for 5 sec.	The supply voltage quality should correspond to that of a typical commercial or hospital environment. If **SIMEX *cuff S*** users require the continued functioning even after the power supply has been interrupted, it is recommended to power the device by means of an interruption-free power supply or a battery.
Magnetic fields with the supply frequency (50Hz) as per IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields with the supply frequency should correspond to the typical values of a commercial and hospital environment.
NOTE: Ut is the a.c. mains voltage prior to application of the test level.			

T 204

Guidance and manufacturer's declaration - electromagnetic immunity

The **SIMEX *cuff S*** is intended for operation in an environment as described below. The customer or the user of the **SIMEX *cuff S*** must ensure that it is operated in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidance
Controlled RF interference quantities according to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile wireless devices should not be used in closer proximity to the **SIMEX *cuff S*** (including cables/lines) than the recommended protection distance calculated based on the transmitting frequency and the applicable formula. Recommended protection distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ for 800 MHz to 2,5 GHz
Emitted RF interference quantities according to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Where "p" is the maximum rated power of the transmitter in watt (W) according to the details from the transmitter manufacturer, and "d" is the recommended protection distance in meters (m). The field strengths from fixed RF transmitters as determined by an electromagnetic site survey[a] should be lower than the compliance level in each frequency range[b]. In the vicinity of equipment labelled with the following symbol, interferences are possible. 

NOTE 1 At 80 MHz and 800 MHz, the protection distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.

a In theory, the field strength of fixed transmitters, e.g. base stations of radio telephones and mobile terrestrial radio devices, amateur radio stations, AM and FM radio and television transmitters cannot be determined in advance. In order to determine the electromagnetic environment with regard to fixed radio transmitters, the conduct of a study of the location should be considered. If the measured field strength exceeds the concordance levels mentioned above at the place where the **SIMEX *cuff S*** is used, the device should be monitored to demonstrate the intended function. If uncommon performance characteristics are observed, additional measures may be required, such as e.g. change of the orientation or a different location of the **SIMEX *cuff S*.**

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

T 206

Recommended protection distances between portable and mobile RF telecommunication devices and the SIMEX *cuff S*.

The **SIMEX *cuff S*** is intended for operation in an electromagnetic environment in which the RF disturbances are controlled. The customer or user of the **SIMEX *cuff S*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF telecommunication equipment (transmitters) and the **SIMEX *cuff S*** as outlined below, depending on the maximum power output of the communication device.

Maximum rated power output of the transmitter (W)	**Protection distance depending on the transmission frequency (m)** 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 whose rated power is not stated in the table above, the recommended safe distance d in metres (m) can be calculated using the equation for the relevant column, where P is the maximum rated power of the transmitter in watt (W) according to the information provided by the manufacturer of the transmitter.

NOTE 1 For 80 MHz and 800 MHz, the protection distance for the higher frequency range applies.

NOTE 2 These guidelines may not be applicable to all cases. Electromagnetic propagation is affected by the absorption and reflections of building, objects and people.

8 List of Replacement Parts and Accessories

REF	Item description	PU
100442	Charger for **SIMEX** and **SIMEX**	1
100414	External Rigid Canister for disposable liners	1
100509	Collection bag (Liner), single use	60
100416	Canister Holder **SIMEX**	1
100012	DFS "Internal" Double Filter System Replacement	1
20102	Filter / Tube Set pump to canister	1
100484	Universal Holder **SIMEX**	1
100346	IV-Pole Holder **SIMEX**	1
100396	Trolley, 5 castors with two brakes	1
100501	Carrying Bag, for **SIMEX** , single use	1
12203	PVC Suction Tubing CH25 with clamp, sterile	50

9. Declaration of conformity

SIMEX Medizintechnik GmbH herewith confirms that the **SIMEX *cuff S*** device corresponds to the following harmonised standards:

- EN 980
- EN 1041
- EN ISO 10993-1
- EN ISO 10079-1
- EN ISO 14971
- EN 60601-1-1 / -2 / -4 / -6 / -8

CE0483.
A detailed declaration of conformity can be obtained from SIMEX Medizintechnik GmbH.

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