Instructions for Use
ASSKEA procuff® M and ASSKEA procuff® S

CE 0494

MEDICAL — GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012);
CAN/CSA C22.2 No. 60601-1:14;
IEC 60601-1-6 (2010) + AMD1(2013);
CAN/CSA-C22.2 No. 60601-1-6:11+ Am1: 2015;
ANSI/AAMI/IEC 60601-1- 8 (2006) + Am.1 (2012);
CAN/CSA-C22.2 No. 60601-1-8:08 + Am1:14;
ANSI/AAMI HA60601-1-11:15;
CAN/CSA-C22.2 No. 60601-1-11:15

GA27-28 / Revision K / 2020-12

The safety of the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** complies with the acknowledged rules of technology and meets the requirements of the **German Medical Devices Act**.
The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** bear the **CE marking CE0494** in accordance with EU Council Directive 93/42/EEC concerning medical devices and meet the essential requirements of Annex I of this directive.
The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** have been tested in accordance with IEC 62353.
The **quality management system** applied by ASSKEA GmbH is certified in compliance with the relevant international standards.
The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** are medical suction devices classified as class IIa in accordance with EU Council Directive 93/42/EEC, Annex IX.

Errors and omissions excepted.

Contents

1 Notes on delivery damage and customer feedback

Caution!

Please, check consignments for damage immediately upon delivery and remove any packaging. All damages must be confirmed by the deliverer and must be reported within three days. Otherwise they cannot be accepted.

The products described in this instruction for use are subjects to constant development and improvement. For this reason, we welcome all customer feedback, comments and suggestions regarding our products and their instruction for use, which contribute to improving the product, service or documentation.

Contact:
mps@asskea.de

2 User information

2.1 Using these instructions for use

Please read these instructions for use carefully before operating the **ASSKEA pro*cuff*® M and the ASSKEA pro*cuff*® S** device for the first time. The device can be operated by both trained medical professionals and relatives of patients, providing they have also undergone appropriate training. If this is the case all functions can be used safely. If support is required for startup, operation or maintenance, please contact ASSKEA GmbH
(see Section 11). Please also report unexpected operating performance or incidents to ASSKEA GmbH (mps@asskea.de).

Please read the safety instructions (Section 2.6) to avoid hazards.
These instructions for use are a component of the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S**.
Keep these instructions for use in an easily accessible place.
Include these instructions for use when passing the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** device on to third parties.

2.2 Icons

2.2.1 Device, packaging and accessories

Symbol	Meaning	Symbol	Meaning
	**Caution:** possible bodily injury, health risks or damage to property.		**NOTE** Note containing useful information and tips.
	Protect from moisture		International Protection: **IP33** (see Section 2.4)
	Protection class II		Order number
	Humidity limitation		Serial number
	Air pressure limitation		Lot number
	Follow the instructions for use		Date of manufacture
	Follow the instructions 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

2.2.2 Display

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

2.3 Symbol convention

Symbol	Meaning
•	Bulleted list
1. 2.	Perform the process in the specified sequence.

2.4 Glossary

A	
approx.	Abbreviation for “approximately”
Aspirate	Aspirate is the generic term for secretions, bodily fluids and flushing liquids that are typically accumulated during aspiration of the upper airways. These can be aspirated easily using the device 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 **ASSKEA pro*cuff*® S**) An external filter and an internal bacterial filter 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.
Degree of protection	The degree of protection indicates the protection of applied parts against electric shock. Applied parts of type BF have to be installed isolated from earth and are not suitable for direct application to the heart.
E	
e.g.	For example, abbreviation for Latin “exempli gratia”
I	
incl.	Abbreviation for “including”
IP33	International Protection / Protection Class The Protection Class defines the degree of protection of the device against contact and ingress of liquids. The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** are protected against solid objects ≥ 2,5 mm diameter and sprays of water from any direction, even if the case is disposed up to 60° from vertical
M	
ME-system	Abbreviation for “Medical electrical system”
MRI	Abbreviation for “magnetic resonance imaging” This technique generates sectional images of the human body with the aid of a very strong magnetic field for the purpose of analyzing the organs.
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 means that all parts that have (potentially) come into contact with the aspirate must be cleaned, disinfected and replaced, if necessary. Reconditioning may only be performed by ASSKEA GmbH or by a service partner authorized by ASSKEA GmbH.
R	
resp.	Abbreviation for “respectively”

2.5 Purpose

2.5.1 Intended use

The **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** device is a network-independent mobile medical device for subglottic aspiration of aspirate with a cuff cannula or a cuff tube with exhauster.

Typical areas of application are:

- in outpatient and inpatient care (professional healthcare facility environment),
- in the homecare sector (home healthcare environment), especially for the aspiration of aspirate with a cuff cannula or a cuff tube with exhauster.

The **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** must never be used simultaneously on more than one patient!

2.5.2 Essential functions

- Generation of a vacuum (medium vacuum)
- Generation of volumetric flow (low flow)

2.5.3 Applied parts

The suction tube is an applied part of type BF.

2.5.4 Indications

- Subglottic aspiration

2.5.5 Contraindications

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** are contraindicated for the following applications:

- Liposuction
- Gynecology applications
- Dental applications
- Applications in wound areas
- Thoracic drainage
- Continuous drainage
- Pharyngeal aspiration

2.5.6 Restrictions on use

- In medical rooms where potential equalization is necessary (e.g. heart surgery)
- In areas subject to explosion hazards / in the MRI environment
- Outside / outdoors

2.6 Basic safety instructions – Caution!

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 for connecting the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** is suitable for 100 V to 240 V AC and a mains frequency of 50-60 Hz.
- 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 AC.
- Only use the power supply unit supplied with the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** (Type: ATM024T-W120V).

Caution when using under conditions that are not approved

- The devices are not intended to be used outside / outdoors.
- The devices are not intended to be used in medical rooms where potential equalization is required (e.g. heart surgery).
- The devices are not intended to be used in areas subject to explosion hazards / in the MRI environment.

Health risks due to the handling of infectious or pathogenic germs

Infectious and pathogenic germs in the aspirate cause health risks.

- Always aspirate with a cuff cannula or a cuff tube with exhauster. The suction tube must never come into contact with the aspiration area.
- Follow the hygiene, cleaning and decontamination instructions.

Risk to persons due to strangulation

- People may strangle themselves on the tubing or the mains cable, especially, if tubes resp. cables are unduly long.
- Ensure that no unauthorized / uninvolved personnel are near the device during aspiration.
- Store the device incl. accessories in the shipping carton.

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 Section 9)

Risk to persons due to improper handling

- Only use the devices for its intended purpose.
- Never use the devices for aspiration in wound areas.
- Never use the devices for thoracic drainage.
- When using the power supply unit, ensure that it is connected to the suction unit firstly and then to the mains supply (100 V to 240 V AC).
- The disconnection of the power supply unit from the mains supply must be performed in exactly the opposite sequence (first remove the power supply unit from the mains supply (100 V to 240 V AC) and then remove it from the suction unit).
- Never touch parts of devices other than ME devices in the patient environment and the patient simultaneously.

Safety defects due to improper accessories and spare parts

The use of accessories and spare parts that are not recommended by ASSKEA GmbH may compromise the safety and function of the devices. Any warranty is excluded for damage caused by using non-recommended accessories and spare parts or by improper use. Only use original accessories and spare parts.

Warning of safety defects due to improper connections of the ME system

The connection of the ME system with other devices, installations or pieces of equipment not recommended by ASSKEA GmbH and not specified in the instructions for use may compromise the safety and function of the ME system. Any warranty is excluded for damage caused by connecting devices, installations or pieces of equipment not recommended for use with the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** or by improper use.

Only connect recommended original parts with the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S.**

Damage to the device caused by heat

- Do not cover the power supply unit.
- Keep the device, the mains cable and the power supply unit away from other heat sources.
- Do not place the devices directly adjacent to other devices, since this can cause the devices to overheat.

Damage to the device due to improper handling

- Never aspirate flammable, corrosive or explosive liquids or gases.
- Do not drop the device.
- Prior to each use check the housing for any damage and do not operate the device in the event of apparent housing damage.
- Prior to each use check the suction tube and secretion canister, and if applicable, any other accessories that are subject to wear and damage, to ensure that the components are in a perfect condition and proper operation of the devices is guaranteed. If this is not the case, replace the parts immediately.

Inspection of the internal power supply

Since the internal battery is not automatically maintained in a fully operational state, it is necessary to check the charging status regularly and, if necessary, the battery must be replaced by service personnel. The battery may only be replaced by trained service personnel, since replacement by inadequately trained personnel could result in a hazard (such as excessive temperatures, fire or explosion)!

Risk of application below non-approved air pressure conditions

If the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** is operated at an air pressure of less than 825 hPa, the maximun vacuum of -300 mbar can no longer be achieved. However, this does not affect safety and functioning of the device.

overview air pressure at 15 °C:

air pressure	height above sea level
1013 hPa	0 m
900 hPa	1000 m
825 hPa	1700 m
746 hPa	2500 m
700 hPa	3000 m

Damage to the device caused by ingress of liquids

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** have the IP classification IP33 in respect of the ingress of liquids. Nevertheless, protect the device from moisture.

- 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 it is switched off).

Possible physiological effects and unobvious risks

- To avoid injuries to the person, select the vacuum range depending on the respective patient and the medical indication.
- Always place the devices upright on a sturdy, flat, non-sloping base. Ensure that the device cannot be knocked over or fall in such a way that persons could be hit by the falling device.
- Other devices, examinations or treatments may possibly be influenced by the devices. For this reason, special attention should always be paid to other devices as well as to examinations and treatments performed in parallel so that any influence is detected as soon as possible.
- When using the devices, adequate lighting must always be ensured so that all labels can be identified clearly.
- Small, detached parts could be inhaled or ingested. Therefore ensure that no unauthorized persons, children or pets are near the device.
- Although the materials used have been tested for compatibility, in exceptional cases allergic reactions to the exposed materials on the device and its accessories may occur. This applies especially to contact injuries after prolonged exposure. In such cases, seek medical assistance immediately.

Known, identifiable or foreseeable conditions for medical care within a domestic environment

- Children and pets should be kept away from the device. Ensure that the device cannot be knocked over or fall in such a way that persons could be hit by the falling device.
- Prior to connecting the power supply unit, ensure that the voltage of the device corresponds to the domestic power supply.
- The device may not be used in damp rooms, bathrooms or showers. Avoid wet conditions on power supply unit, control panel and socket for the power supply unit.
- Ensure that fluff and dust are immediately removed from the device and accessories, in order to ensure unimpaired functionality. Furthermore, pests should be prevented from being in the vicinity of the device, as there is a risk they may get inside the device and cause damage.
- Never expose the device or accessories to direct sunlight as this could result in overheating and cause functional impairments.
- Unfavorable light conditions may affect legibility of the display.
- Some devices and sources that are commonly used in the domestic environment may potentially cause faults in the device or accessories, e.g. fireplaces or radiant heaters (overheating of the device) resp. inhalers or steam kettles (excessive air humidity). Do not operate such devices and sources in the vicinity of the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S.**

2.7 User requirements

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** may only be operated and used by instructed and trained personnel. Familiarize yourself with the mode of operation of the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** prior to startup.

Training on how to handle the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** is provided by ASSKEA GmbH or an authorized distribution partner of ASSKEA GmbH. Product training takes approximately one to two hours and, among other things, includes an explanation of the design and function of the device, the handling of the device, the cleaning and disinfection as well as the procedure to be followed for each new patient and for disposal.

The training should be repeated regularly every 24 months.
Each participant receives a certificate as proof of training.

2.8 Information on product liability

The liability for the functioning of the device is transferred 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,
- the safety seal is removed / broken,
- installation, settings, enhancements, routine maintenance or repairs are performed by unauthorized personnel,
- original accessories and spare parts have not been used.

Advice for the responsible organization:
The assembly of ME systems and modifications during their expected service life shall be evaluated based on compliance with the requirements of the applicable standards.

2.9 Material compatibility

Aggressive substances may damage the device and accessories.
Follow the cleaning and care instructions (Section 5.1)

3 Product Description

3.1 Overall view of the ME system

3.1.1 ASSKEA pro*cuff*® M

Fig. 1 ASSKEA procuff® 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 **ASSKEA pro*cuff*® M** device
G Socket for power supply unit

3.1.2 ASSKEA pro*cuff*® S

Fig. 2 ASSKEA procuff® S

A Disposable secretion canister system (1 l)
B Holder for external canister “Bag”
C Connecting tube
D Display
E Control panel ((OK) (On) and (C) (Off) buttons and (▲) and (▼) arrow buttons)
F **ASSKEA pro*cuff*® S** device
G Socket for power supply unit

3.2 Scope of delivery

3.2.1 Scope of delivery ASSKEA pro*cuff*® M

- the device ASSKEA pro*cuff*® M
- these instructions for use
- 2 x disposable secretion canister (250 ml) with integrated bacterial filter, carbon filter, solidifier and suction tube with step connector
- power supply unit (Type: ATM024T-W120V) 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)

A separate Quick Reference Guide for use of the **ASSKEA pro*cuff*® M** in the homecare sector is available for download on our website (www.asskea.de) under “Download”.

3.2.2 Scope of delivery ASSKEA pro*cuff*® S

- the device ASSKEA pro*cuff*® S
- these instructions for use
- disposable secretion canister system
  (comprising the external canister “Bag”, disposable liner “OneWay”, holder for external canister “Bag”, connecting tube and disposable suction tube (sterile) with step connector)
- power supply unit (Type: ATM024T-W120V) 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)

A separate Quick Reference Guide for use of the **ASSKEA pro*cuff*® S** in the homecare sector is available for download on our website (www.asskea.de) under “Download”.

3.3 Product Properties

Risk to persons due to improper handling.

- Use the device for its intended use only.
- Never use the device for aspiration in the low-vacuum range (e.g. thoracic drainage).

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 the event of apparent housing damage.

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** devices are lightweight, portable, battery-powered medical aspirators for in-patient and mobile use in the medical, subglottic aspiration of aspirate in combination with a cuff cannula or a cuff tube with exhauster. It is intended for aspiration in the medium-vacuum range and can be used in hospitals, medical practices and even in the homecare sector.
The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** has a max. flow rate of 8 l/min (see Section 8 “Technical data”).

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** devices are operated via the internal battery or via the supplied power supply unit, which can also be used to recharge the battery. An overheating safety mechanism also prevents overheating of the battery by interrupting the charging process if the battery temperature gets too high (e.g. due to unfavorable ambient conditions).

The vacuum is generated by a maintenance-free electric motor-driven diaphragm 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 a cuff cannula or a cuff tube with exhauster). The aspirate 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 **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** devices must only be operated with the supplied disposable secretion canister (system).

The provided disposable secretion canister for the **ASSKEA pro*cuff*® M** as well as the disposable liner “OneWay” and the suction tube for the **ASSKEA pro*cuff*® S** are intended for single use.

3.3.1 Disposable secretion canister for ASSKEA pro*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 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 interrupted. The disposable secretion canister must be replaced.
The activated carbon filter in the disposable secretion canister reduces the spread of odors.

Solidifier:
Disposable secretion canisters which are full of aspirate can be transported and disposed of 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), irrespective of the aspiration intervals.

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

3.3.2 Information on the ASSKEA filter system for the ASSKEA pro*cuff*® M

The filter system of the **ASSKEA pro*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 in combination with the integrated filter.

The ASSKEA 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 aspirate (blocked), after the filter service life has expired** ([!] symbol in the display) or during **maintenance / repair**.

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

3.3.3 Information on the carbon filter of the ASSKEA pro*cuff*® M

An additional filter in the exhaust air vent of the **ASSKEA pro*cuff*® M** neutralized undesirable odors in the exhaust air of the device. This filter consists of a thin nonwoven material coated activated carbon. The activated carbon in the nonwoven absorbs the odor particles from the exhaust air and neutralizes them. This effectively reduces the spreading of odors.

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 ASSKEA GmbH or an authorized service partner of ASSKEA GmbH.

3.3.4 Disposable secretion canister system for ASSKEA pro*cuff*® S

The disposable secretion canister system consists of the external canister “Bag”, the disposable liner “OneWay”, the holder for the external canister “Bag”, the connecting tube and the disposable suction tube. The disposable liner “OneWay” has an integrated, self sealing bacterial filter, carbon filter and solidifier. The integrated filter prevents 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 interrupted. The disposable liner “OneWay” must be replaced.
The activated carbon filter in the disposable liner “OneWay” reduces the spread of odor.

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

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

3.3.5 Information on the double filter system for ASSKEA pro*cuff*® S

The ASSKEA double filter system DFS® consists of the external bacterial filter integrated in the disposable liner “OneWay” and the internal filter installed in the device. The filters are hydrophobic and self-sealing bacterial filters.
The internal bacterial filter is installed in the **ASSKEA pro*cuff*® S**.
The external bacterial filter is incorporated in the disposable liner “OneWay”.

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

Service life and reuse

The internal filter of the ASSKEA double filter system DFS® and the disposable liner “OneWay” are not intended for reuse. To ensure consistent performance, the internal filter must be replaced **prior to each new patient, after contact with the aspirate (blocked), after the filter service life has expired** (symbol in the display) or during **maintenance / repair**.

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

3.3.6 Information on the battery

Inspection of the internal power supply

- Since the internal battery is not automatically maintained in a fully operational state, it is necessary to check the charging status regularly and, if necessary, the battery must be replaced by service personnel.
- The battery may only be replaced by ASSKEA GmbH or by a servicepartner authorized by ASSKEA GmbH, since the replacement by inadequately trained personnel could result in a hazard (such as excessive temperatures, fire or explosion)!

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 **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** and to repeat this after the first uses.

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

The **ASSKEA pro*cuff*® M and ASSKEA pro*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 an extended 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.
Frequent short-time charging should be avoided.

The battery of the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** is protected against deep discharging, but the charging information above must 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.

According to the manufacturer of the battery, the battery has a remaining capacity of more than 80% after 300 charge cycles.

3.3.7 Pressure settings

Once the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** have 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). The setting of the pressure and time values is described in Section 4.3.

Always use the lowest possible pressure setting. Adjustments to device settings should only be made on the instruction of healthcare professionals.
Prior to switching on the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**, it must be ensured that the device is equipped with a disposable secretion canister.

3.4 Warranty

WARNING: Modifications of the ME device are not permitted.

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** 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.

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

- original ASSKEA accessories and replacement parts are used,
- maintenance and repair are performed by professionals authorized by ASSKEA GmbH or by ASSKEA GmbH itself,
- the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** is used and operated in accordance with the instruction for use and for its intended use.

All warranty claims shall be void, if:

- the device is opened by unauthorized personnel,
- the safety seal is removed / broken,
- repairs are performed by unauthorized personnel,
- modifications are made to the device,

since the basic safety of the device can no longer be guaranteed in these cases and functional limitations may occur.

4 Operation

Risk to persons due to improper handling.

- Use the device for its intended purpose only.
- Please read Sections 4.1 to 4.6 carefully!
- Perform the subglottic aspiration only after instruction by trained personnel!
- Use exclusively a cuff cannula or a cuff tube with exhauster for aspiration!

Malfunction due to aspirated aspirate

- Ensure that the disposable secretion canister of the **ASSKEA pro*cuff*® M** and the disposable liner "OneWay" of the **ASSKEA pro*cuff*® S** is replaced on a regular basis. If the disposable secretion canister or the disposable liner "OneWay" is full, the integrated overflow protection system is triggered and the alarm "Syst. closed – canister full" is activated. This disrupts the aspiration process.
- Switch off the device when replacing the disposable secretion canister or the disposable liner "One Way".
- If the internal filter of the **ASSKEA pro*cuff*® M** or the DFS® of the **ASSKEA pro*cuff*® S** is blocked, the device must be properly processed by ASSKEA GmbH or by an authorized service partner of ASSKEA GmbH!

Risk to persons during operation in a domestic environment

Due to the increasing mobility of patients in a domestic environment, there is an increasing risk that the secretion will not be properly aspirated out of the subglottic area and that the therapy process will therefore be sub-optimal. For this reason, the detailed training and instruction of patients as well as the performance of regular monitoring of the aspiration system by trained personnel, is mandatory.

Damage to the device due to insufficient acclimatization

After the devices have been exposed to temperatures between -25 °C and +60 °C (beyond ambient temperatures) during transport / storage according to the technical data (see Section 8), they must first acclimatize for approx. 2 h at room temperature (approx. 20 °C) before the intended use is possible.

4.1 Setup and startup

The following sections describe the operating elements, connections and the startup of the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S**:

4.1.1 Connecting the ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S

Known or identifiable conditions for medical care within a domestic environment

- Children and pets should be kept away from the device to ensure that it cannot be knocked over or dropped.
- Prior to connecting the power supply unit, ensure that the voltage of the device corresponds to the domestic power supply.
- The device may not be used in damp rooms, bathrooms or showers. Avoid wet conditions on power supply unit, control panel and socket for the power supply unit. Never submerge the device in water or other liquids (even when it is switched off).

Check the power supply unit and mains cable for possible damage before each use and replace it if there is any damage.

Use the socket for the 12V power supply unit of the **ASSKEA pro*cuff*® M** (Section 3.1.1, fig. 1 (G)) or the socket for the power supply unit of the **ASSKEA pro*cuff*® S** (Section 3.1.2, fig. 2 (G)) to connect the device to the mains power supply via the supplied power supply unit (type: ATM024T-W120V) for charging or operation as required.
Ensure that the device is positioned in such a way that it is possible to easily disconnect it later.
Information on the permissible environmental conditions during operation can be found in Section 8 “Technical data”.

Use the supplied power supply unit only. First connect the power supply unit to the socket for power supply unit of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** and then to the mains power supply.

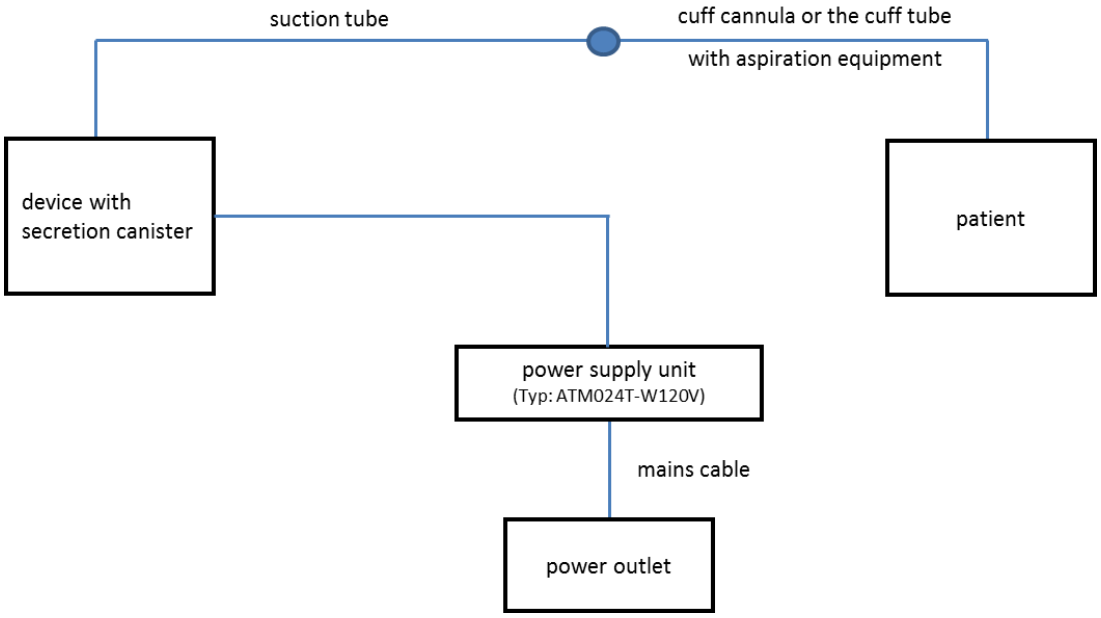


Fig. 3 Connecting the ASSKEA procuff® M and ASSKEA procuff® S to the patient and accessories

4.2 Startup

It is important to follow the safety instructions set out in Section 2.6 prior to initial startup. Always have a backup disposable secretion canister for the **ASSKEA pro*cuff*® M** and a backup disposable liner “OneWay“ (1 l) for the **ASSKEA pro*cuff*® S** ready, since these are essential for safe operation!

- Please read through these instructions for use before operating the device for the first time.
- Remove the device and the accessories from the packaging.
- Please read thorugh these instructions for use before operating the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** device for the first time.
- Always place the device on a sturdy and flat surface. Ensure the device is positioned correctly.
- Fully charge the battery prior to initial startup.
- Inspect all tubing as well as the power supply unit for damage prior to each startup of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**. It is important to avoid kinking when connecting the tubing. Prior to switching on the unit, ensure that the disposable secreiton canister resp. disposable liner “One Way” and tubings are properly connected.
- Perform a function test! (Please refer to Section 6.1)

4.2.1 Positioning of the ASSKEA pro*cuff*® M

The **ASSKEA pro*cuff*® M** can be placed next to the patient bed or attached by means of a variable holder for tube and rail systems. An optional carrying bag is available for portable use (only for **ASSKEA pro*cuff*® M** with a 250 ml canister). It is, however, up to the physician to decide whether the condition of the patient permits portable use. The **ASSKEA pro*cuff*® M** with a 250 ml canister can also be used in a horizontal position:

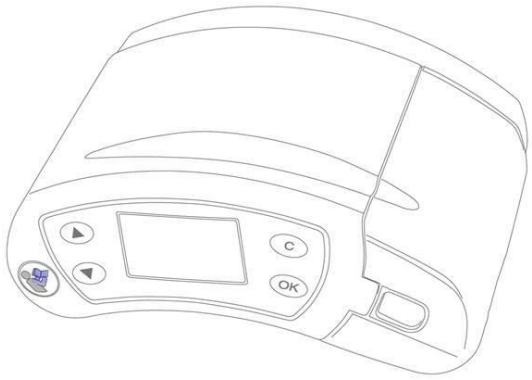


Fig. 4 ASSKEA procuff® M used horizontally

To ensure optimum aspiration of the aspirate, place the **ASSKEA pro*cuff*® M** below the suction point. It should be noted that the suction tube does not form a dip and is situated at least at patient level.

4.2.2 Connecting the disposable secretion canister of the ASSKEA pro*cuff*® M

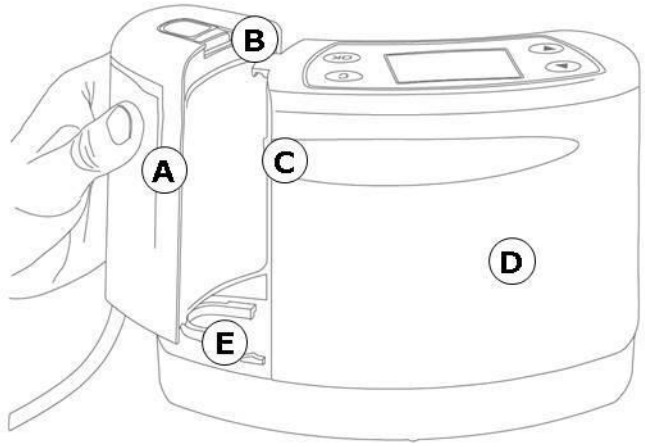


Fig. 5 Connecting the disposable secretion canister

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

1. Remove the disposable secretion canister (fig. 5 (A)) from the packaging.
2. Slide the canister onto the guide rail (fig. 5 (E)) of the **ASSKEA pro*cuff*® M** until the disposable secretion canister clicks into place in the locking mechanism (fig. 5 (B)).

4.2.3 Positioning of the ASSKEA pro*cuff*® S

The **ASSKEA pro*cuff*® S** can be placed next to the patient bed. Optionally, a variable holder for attaching the device to tube and rail systems as well as a bed holder is available.

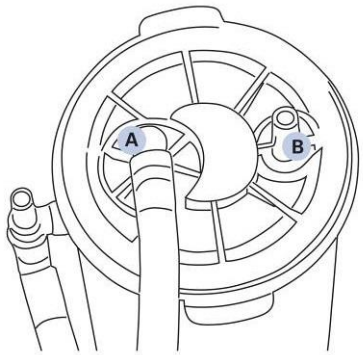
To ensure optimum aspiration of the aspirate, place the **ASSKEA pro*cuff*® S** below the suction point. It should be noted that the suction tube does not form a dip and is situated at least at patient level.

4.2.4 Connecting the ASSKEA disposable secretion canister system of the ASSKEA pro*cuff*® S

Malfunction due to collapsing disposable liner “OneWay”.
A leak in the external canister “Bag” or in the lid of the disposable liner “OneWay” may cause air to flow into the external canister “Bag”. This may lead to the collapse of the disposable liner “OneWay”.

- Inspect the disposable secretion canister system (1 l) to ensure that the lid of the disposable liner “OneWay” is firmly connected to the external canister “Bag”.
- Ensure that all connections are firmly attached and properly connected.
- Ensure that the external canister “Bag” is undamaged and the T-piece is firmly attached.

The original ASSKEA disposable secretion canister system consists of the external canister “Bag”, the holder for the external canister “Bag”, the disposable liner “OneWay”, the connecting tube for the disposable liner “OneWay” 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 l)!

Fig. 6

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

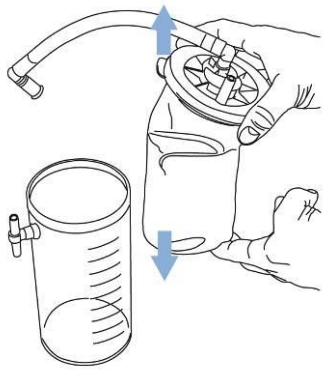


Fig. 7

2. Place the disposable liner “OneWay” in the reusable external canister “Bag”. Press the lid’s edges firmly down to ensure proper sealing.

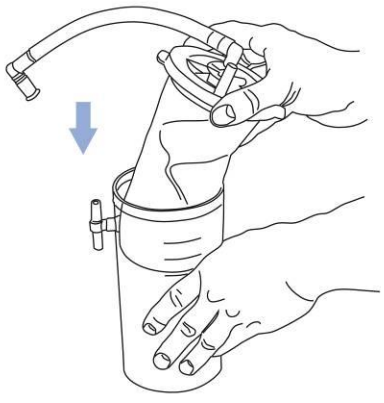


Fig. 8

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

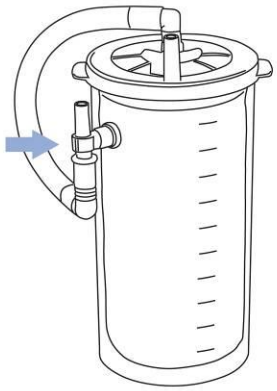


Fig. 9

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

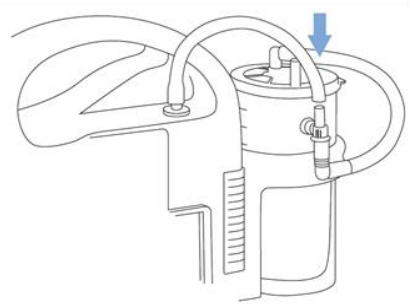


Fig. 10

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

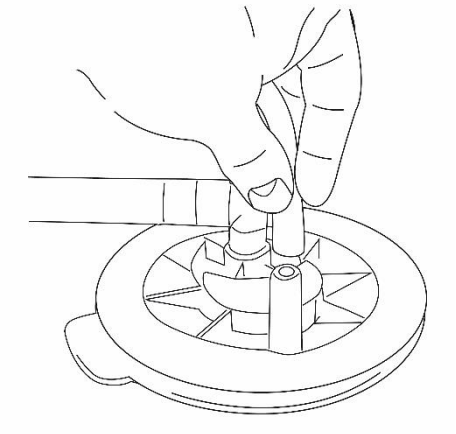


Fig. 11

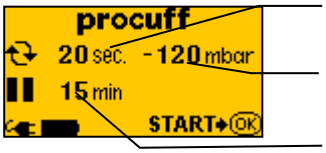
4.2.5 Connecting a cuff cannula or cuff tube with exhauster

Connect the suction tube of the disposable secretion canister to the exhauster of the cuff cannula or cuff tube. The suction tube must never come into direct contact with the aspiration area.

4.3 Operation of the ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S

1. Press the (OK) button for 1-2 seconds to switch on the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**. The following start screen is displayed for 5 seconds:

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



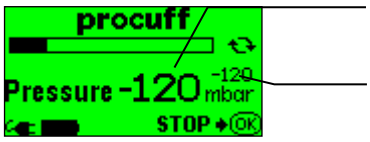
Run time

Target value

Pause time

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

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

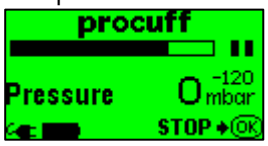


Actual value

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 voids from the right to the left and shows the pause time.

5. Press the (OK) button to stop the therapy.

6. You will return to the overview screen:

7. Switch off the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** by pressing the (C) button for 3 seconds.

To aspirate without pause in the event of a high rate of aspirate 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.

4.3.1 Setting the run and pause time

The **ASSKEA pro*cuff*® M and ASSKEA pro*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 **ASSKEA pro*cuff*® M resp. ASSKEA pro*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.

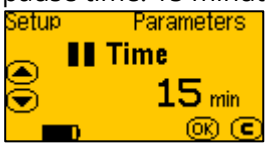
3. Select the menu Parameters with the ▲▼ arrow buttons.

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.

4.3.2 Language selection

The **ASSKEA pro*cuff*® M and ASSKEA pro*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:

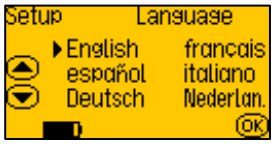
1. Press the OK button for 1-2 seconds to switch on the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**. The following start screen is displayed for 5 seconds:

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.

4.4 Patient mode

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** enable the selection of the patient mode at startup. In patient mode, the patient runtime can be viewed and reset and the alarm “System closed” can be disabled or enabled.
The alarm “System closed” is generally disabled at delivery. It is intended for monitoring the aspiration flow and for signaling blockages in the tubing system or the exhauster.
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 **ASSKEA pro*cuff*® M resp. ASSKEA pro*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 “xxxx” 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.

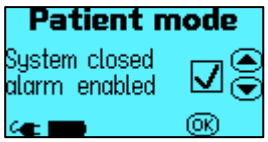
The authorization code for patient mode may only be passed to specially trained personnel. You will get the training and the authorization code from ASSKEA GmbH or an authorized distribution partner of ASSKEA GmbH.

Passwords must be treated as confidential information to prevent misuse.

4. After authorization, the patient runtime is displayed.

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

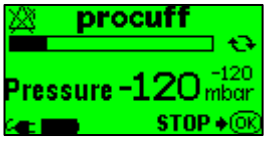
6. Press the OK button to get to the following screen to enable the alarm “System closed”:



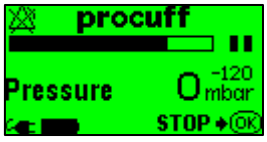
7. Press the ▲▼ arrow buttons to enable or disable the alarm “System closed”.

If the alarm “System closed” is disabled this setting will be shown in the display as follows:

Overview screen



Run time



Pause time

Note that, if the alarm “System closed” is disabled, monitoring of the aspiration flow and detection of blockages in the suction system are no longer recognizable by the user. The pressure in the pause time will be monitored and the system will be ventilated automatically if the pressure drop is too low, even if the alarm is disabled. However, this is no longer visible to the user, so that it is not possible to perform necessary countermeasures.

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

4.5 Canister replacement

4.5.1 Replacement of the disposable canister of the ASSKEA pro*cuff*® M

Health risks due to the handling of infectious or pathogenic germs

Infectious and pathogenic germs in the aspirate cause health risks.

- Wear suitable disposable gloves when replacing the disposable canister.
- Use the disposable secretion canister for one patient only.
- Replace the disposable secretion canister if it is full, prior to each new patient or weekly at the latest, in accordance with the applicable hygiene instructions.
- For each new patient, processing by ASSKEA GmbH or by an authorized service partner of ASSKEA GmbH is mandatory!
- After each aspiration procedure, all components that have come into contact with the aspirate must be cleaned, disinfected or disposed of.
- The aspirate and the parts contaminated with aspirate must be disposed of properly.

1. Switch off the ASSKEA pro*cuff*® M.
2. Close the tubing clamp of the suction tube.
3. Separate the suction tube from the exhauster of the cuff cannula or cuff tube.
4. Press on the locking mechanism at the top of the canister (fig. 5 (B), p. 21) 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 Section 7.3 “Disposal”)
6. Place a new disposable secretion canister on the device according to Section 4.2.2. Ensure that the disposable secretion canister is properly connected to the device.
7. Connect the suction tube to the exhauster of the cuff cannula or cuff tube.
8. Switch on the ASSKEA pro*cuff*® M.

4.5.2 Replacement of the disposable liner “OneWay” of the ASSKEA pro*cuff*® S

Health risks due to the handling of infectious or pathogenic germs

Infectious and pathogenic germs in the aspirate cause health risks.

- Wear suitable disposable gloves when replacing the disposable liner “OneWay”.
- Use the disposable liner “OneWay” for one patient only.
- Replace the disposable liner “OneWay” if it is full, prior to each new patient or weekly at the latest, in accordance with the applicable hygiene instructions.
- For each new patient, processing by ASSKEA GmbH or by an authorized service partner of ASSKEA GmbH is mandatory!
- After each aspiration procedure, all components that have come into contact with the aspirate must be cleaned, disinfected or disposed of.
- The aspirate and the parts contaminated with aspirate must be disposed of properly.

1. Switch off the ASSKEA pro*cuff*® S.
2. Close the tubing clamp of the suction tube.
3. Remove the suction tube from the exhauster of the cuff cannula or cuff tube.
4. Separate the pre-assembled connecting tube of the disposable liner “OneWay” at the bottom end of the T-piece of the external canister “Bag”.
5. Remove the disposable liner “OneWay” from the reusable external canister “Bag”.
6. Dispose of the disposable liner “OneWay” incl. the suction tube in a properly manner. (Please refer to Section 7.3 “Disposal”)
7. Place a new disposable liner “OneWay” in the reusable external canister “Bag” as specified in 4.2.4. Ensure that the connecting tube and 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 “OneWay” and connect it to the exhauster of the cuff cannula or cuff tube.
9. Switch on the ASSKEA pro*cuff*® S.

4.6 Decommissioning

Health risks due to the handling of infectious or pathogenic germs

Infectious and pathogenic germs in the aspirate cause health risks.

- Wear suitable disposable gloves.
- The reuse of bacterial filters for multiple patients is prohibited for hygiene and safety reasons!
- For each new patient, processing by ASSKEA GmbH or by an authorized service partner of ASSKEA GmbH is mandatory!
- After each aspiration procedure, all components that have come into contact with the aspirate must be cleaned, disinfected or disposed of.
- The aspirate and the parts contaminated with aspirate must be disposed of properly.

1. Switch off the device after the aspiration by holding the ⓒ button pressed for 3 seconds.
2. Disconnect the power supply unit from the mains supply (100 V to 240 V AC) and then remove the device plug from the **ASSKEA pro*cuff*® M or ASSKEA pro*cuff*® S**.
3. Remove the disposable secretion canister of the **ASSKEA pro*cuff*® M** (as described in Section 4.5.1 up to and including point 5).
4. Remove the disposable liner “One Way” of the **ASSKEA pro*cuff*® S** as described in Section 4.5.2 up to and including point 6. Follow the instructions for cleaning the external canister “Bag” in section 5.1.5.
5. Clean the surface of the device according to section 5.1.2.
6. Store the device in the shipping carton until next operation.

5 Maintenance

5.1 Cleaning and care in outpatient and inpatient care

5.1.1 General Information

Health risks due to the handling of infectious or pathogenic germs.
Infectious and pathogenic germs in the aspirate cause health risks.
- Wear suitable disposable gloves when replacing the disposable secretion canister or the disposable liner “OneWay”.
- Use the disposable secretion canister or the disposable liner “OneWay” for one patient only.
- Replace the disposable secretion canister (**ASSKEA pro*cuff*® M**) or the disposable liner “OneWay” incl. suction tube (**ASSKEA pro*cuff*® S**) if it is full, prior to each new patient or weekly at the latest, in accordance with applicable hygiene instructions.
- For each new patient, processing by ASSKEA GmbH or an authorized service partner of ASSKEA GmbH is mandatory!
- Components that have come into contact with the aspirate must be cleaned, disinfected or disposed of after each aspiration.
- The disposal of aspirate and contaminated components must be performed in a properly manner.

Health risks due to the handling of disinfectants.
- The use of appropriate protective clothing during disinfection is recommended.
- Follow the manufacturer’s disinfectant instructions.

Possible bodily injury due to electric shock.
- Prior to cleaning / disinfection, switch off the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**.
- Disconnect the power supply unit by unplugging it from the power supply. Disconnect the power supply unit from the socket for the power supply unit of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**.

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 instructions for use provided by the manufacturers of the utilized disinfectants, particularly with regard to material and surface compatibility as well as concentration information.
- ASSKEA GmbH recommends `Sekusetp® aktiv´ for immersion disinfection of the accessories and `Incidin® Plus´ and `Incidin® Liquid´ for wipe disinfection of the device.

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

5.1.2 Cleaning and disinfection of the surface of the device

Clean the surfaces of the device regularly and disinfect them daily.

- The device can be wiped with a damp, lint-free cloth.
- Follow the instructions in Section 5.1.1 for wipe disinfection.

Repeated cleaning and disinfection procedures may result in minor discolorations of the plastic components of the housing. However these do not affect the function of the device.

If the interior of the device comes into direct contact with liquids or solids, the device must be inspected by ASSKEA GmbH or by a service partner authorized by ASSKEA GmbH.

5.1.3 Disposal of the disposable secretion canister for ASSKEA pro*cuff*® M

1. Close the suction tube of the disposable secretion canister by using the tubing clamp on the suction tube.
2. Dispose of the disposable secretion canister incl. suction tube in a proper manner (please refer to Section 7.3). It is a single-use item.

5.1.4 Disposal of the disposable liner "OneWay" and the suction tube for ASSKEA pro*cuff*® S

1. Close the tubing clamp of the suction tube (fig. 3).
2. Separate the pre-assembled connecting tube of the disposable liner "OneWay" at the bottom end of the T-piece of the external canister "Bag".
3. Remove the disposable liner "OneWay" from the reusable external canister "Bag".
4. Dispose of the disposable liner "OneWay" incl. the suction tube in a proper manner (please refer to Section 7.3 "Disposal").

5.1.5 Cleaning / disinfection of the external canister "Bag" for ASSKEA pro*cuff*® S

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

1. Rinse the external canister "Bag" under running water.
2. Immerse the external canister "Bag" in disinfectant solution for the specified contact time and concentration.
3. Subsequently rinse the external canister "Bag" thoroughly and allow it to dry.

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

In accordance with applicable hygiene instructions, ASSKEA GmbH recommends replacing the external canister "Bag" **every four weeks** at the latest.

5.1.6 Cleaning / disinfection of the holder for the external canister “Bag“

Clean the surfaces of the holder for the external canister „Bag“ regularly and disinfect them daily. The holder for the external canister “Bag” can be wiped with a damp, lint-free cloth. See Section 5.1.1 for wipe disinfection.

Repeated cleaning and disinfection procedures may result in minor discolorations of the holder for the external canister “Bag”. However these do not affect the function of the devices.

In accordance with the applicable hygiene instructions, ASSKEA GmbH recommends replacing the holder for the external canister “Bag” **every four weeks** at the latest.

5.1.7 Cleaning / disinfection of the tubing accessories for ASSKEA pro*cuff*® S

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

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

In accordance with applicable hygiene instructions, ASSKEA GmbH recommends replacing the connecting tube **every four weeks** at the latest.

5.2 Cleaning and care in the homecare sector

5.2.1 General information

Health risks due to the handling of infectious or pathogenic germs
Infectious and pathogenic germs in the aspirate cause health risks.

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

Health risks and damages to the device due to the handling of disinfectants
If you are able to use disinfectants, please note the information set out in Section 5.1. Otherwise, please see the information set out in sections 5.2.2 to 5.2.7!

5.2.2 Cleaning of the surface of the device

Clean the surfaces of the device regularly.

The device can be wiped with a damp, lint-free cloth. Repeated cleaning procedures may result in minor discolorations of the plastic components of the housing. However these do not affect the function of the device.

If the interior of the device comes into direct contact with liquids or solids, the device must be inspected by ASSKEA GmbH or by a service partner authorized by ASSKEA GmbH.

5.2.3 Disposal of the disposable secretion canister for ASSKEA pro*cuff*® M

1. Close the suction tube of the disposable secretion canister by using the tubing clamp on the suction tube.
2. Dispose of the disposable secretion canister incl. suction tube in a proper manner (please refer to Section 7.3). It is a single-use item.

5.2.4 Disposal of the disposable liner “OneWay” and the suction tube for ASSKEA pro*cuff*® S

1. Close the tubing clamp of the suction tube (fig. 3).
2. Separate the pre-assembled connecting tube of the disposable liner “OneWay” at the bottom end of the T-piece of the external canister “Bag”.
3. Remove the disposable liner “OneWay” from the reusable external canister “Bag”.
4. Dispose of the disposable liner “OneWay” incl. the suction tube in a proper manner (please refer to Section 7.3 “Disposal”).

5.2.5 Cleaning / disinfection of the external canister “Bag” for ASSKEA pro*cuff*® S

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

1. Rinse the external canister “Bag” under running water.
2. Place the external canister “Bag” in a water bath at 65 °C temperature for 15 minutes once a day.
3. Subsequently rinse the external canister “Bag” thoroughly and allow it to dry.

ASSKEA GmbH recommends replacing the external canister “Bag” **every four weeks,** if it is used and hygienically cleaned / disinfected frequently!

5.2.6 Cleaning / disinfection of the holder for the external canister “Bag“

Clean the surfaces of the holder for the external canister “Bag“ regularly and disinfect them daily. The holder for the external canister “Bag” can be wiped with a damp, lint-free cloth. See Section 5.1.1 for wipe disinfection.
Repeated cleaning and disinfection procedures may result in minor discolorations of the holder for the external canister “Bag”. However these do not affect the function of the devices.

In accordance with the applicable hygiene instructions, ASSKEA GmbH recommends replacing the holder for the external canister “Bag” **every four weeks** at the latest.

5.2.7 Cleaning / disinfection of the tubing accessories for ASSKEA pro*cuff*® S

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

1. Flush the connecting tube (Fig. 2(C)) in clear water or place the connecting tube in a water bath at 65 °C temperature for 15 minutes once a day.
2. Afterwards, rinse the connecting tube thoroughly and let it dry.

ASSKEA GmbH recommends replacing the connecting tube **every four weeks**, if it is used and hygienically cleaned / disinfected frequently!

5.3 Further use of the device

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** are suitable for further use. However, prior to passing the device on to other patients or persons, it has to be processed professionally. For this purpose, please hand the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** over to ASSKEA GmbH or to qualified personnel authorized by ASSKEA GmbH. In this regard, please observe the information set out in Section 7.1!

5.4 Maintenance and servicing

WARNING: Modifications of the ME device are not permitted.

Risk of impairments of performance due to aging effects
If you notice impaired performance of the device or other problems, follow the instructions on troubleshooting in Section 6 and, if necessary, contact the Service.

Risk due to maintenance and service during operation
Maintenance and service must not be performed while the device is in use! The device must be switched off before maintenance and service work is performed.

Risk due to the performance of maintenance and servicing by unauthorized persons
Maintenance and service may only be performed by specialized personnel authorized by ASSKEA GmbH or by ASSKEA GmbH itself.

Risk due to the performance of maintenance and servicing without sufficient documents
Maintenance and servicing may only be performed using the service instructions for the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**. ASSKEA GmbH will also provide additional documents on request, insofar as these may assist service personnel.

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** devices are maintenance-free if used according to the instruction for use, with the exception of components with limited shelf life.

Perform a visual and functional inspection prior to each use (please refer to Section 6.1). Also include the accessories of the device in the inspection.

Opening of the device and repairs may only be performed by ASSKEA GmbH or by an authorized service partner of ASSKEA GmbH in compliance with the servicing documentation provided by the manufacturer as well as technical and hygienic precautionary measures.

The device may be sent back for repair to ASSKEA GmbH directly or via the specialist 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 (Section 7.1).

In order to avoid delays, notify ASSKEA GmbH prior to returning the device and mark the shipping carton of the device with the label “Used Medical Device”.

The corresponding product return form with the “Used Medical Device” label can be found on the ASSKEA GmbH website at www.asskea.de in the service area under product return.
ASSKEA GmbH does not guarantee proper functioning of the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** medical suction devices, nor is ASSKEA GmbH liable for property damage or personal injury if

- original ASSKEA 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 ASSKEA GmbH or authorized personnel of ASSKEA GmbH,
- the safety seal has been removed or is damaged.

5.5 Inspection of the ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S

ASSKEA GmbH offers its partners and customers fast and professional processing as well as mandatory testing services.

6 Troubleshooting

6.1 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 4.3.
2. Start the therapy and allow the device to run without the canister. No alarm should be triggered.
   If the alarm "Syst. closed – canister full" occurs, the internal filter of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** is blocked an should be replaced by service personnel.
3. Press OK button to confirm the alarm.
4. Afterwards hold the tube attachment closed with a finger and restart the therapy. The alarm "Syst. Closed-canister full" must be displayed after no more than 5 seconds. If the alarm is not displayed even after repeating the test, have the device inspected by a service partner.

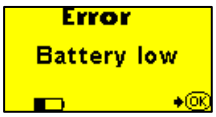
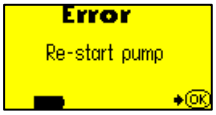
6.2 Troubleshooting

Malfunction	Probable causes	Remedy
Device cannot be started.	• Battery is empty • Display foil is defective	• Connect the power supply unit • Please contact service partner.
Therapy does not start, no flow of aspirate	• Cannula or tube is blocked / kinked	• Check positioning of the cannula and the cuff pressure • Rinse / change the cannula or tube • Adjust the position of the device • Verify proper connection of the tubing
	• Tubing clamp is closed	• Open the tubing clamp
	• Secretion is too viscous	• Please contact your physician / nursing staff
	• Disposable secretion canister or disposable liner "OneWay" is full	• Replace disposable secretion canister (250 ml) (for **ASSKEA pro*cuff*® M**) or replace disposable liner "OneWay" (1 l) (for **ASSKEA pro*cuff*® S**)
	• Internal filter is blocked	• Please contact service partner.
	• Device is still in *Setup* mode	• Finalize the selection (please refer to 4.3) and start the therapy.

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

6.3 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 flashing background and the beeper sounds (3x, pause, 2x, 3x, pause, 2x) every 3 seconds.
- Alarm messages of low priority are shown in the display with a static yellow background and the beeper sounds periodically (2x) every 16 seconds.

Error message	Status	Probable cause	Remedy
	Pump off. Discontinuation of the current operating mode.	Disposable secretion canister (250 ml) is full. Disposable liner “OneWay” (1 l) is full. If the alarm is displayed even if the canister is not connected, the internal bacterial filter is blocked.	Replace the disposable secretion canister (250 ml). Replace the disposable liner “OneWay” (1 l). Contact your service partner!
	Pump off. Discontinuation of the current operating mode.	Battery is empty.	Connect the power supply unit.
	Pump off. Discontinuation of the current operating mode.	Internal error.	Briefly plug in the power supply unit and unplug again. If the error reoccurs 60 seconds after restarting, contact your service partner!
* 	Pump off. Discontinuation of the current operating mode.	Cannula or tube is blocked. Aspiration flow obstructed. (tubing is kinked) Tubing clamp is closed.	Check positioning of the cannula and the cuff pressure. Rinse / change the cannula or tubing. Adjust the position of the device. Open tubing clamp.
	Current operating mode continues to run in the background.	Low battery charge level.	Connect the power supply unit immediately.
	Operating Mode “Stand by” (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 Section 4.4).

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

7 Transport, storage and disposal

7.1 Decontamination prior to shipment

Prior to passing on the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** to other, new users, the devices must be properly processed by ASSKEA GmbH or by an ASSKEA GmbH authorized service partner 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.

ASSKEA GmbH offers its partners and customers fast and professional processing as well as mandatory testing services (please refer to Section 5).

The **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** devices must be cleaned and disinfected prior to shipment to ASSKEA GmbH. Please follow the instructions set out in Section 5! Please affix the supplied "Used Medical Device" label to the shipping carton! Please give ASSKEA GmbH advance notice of your product return. The product return form is provided on our website at www.asskea.de in the service area under product return.

7.2 Storage

Store the **ASSKEA pro*cuff*® M and ASSKEA pro*cuff*® S** devices as indicated in the technical data (Section 8)!
Store the device in the shipping carton until next operation.

The battery of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** suction 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 **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** device is not used for an extended period of time (approx. 10 months).

7.3 Disposal

- The disposal of the device and of the accessories must be carried out in a proper manner.
- 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 is registered in the national register for waste electric equipment (EAR foundation) as a small electrical device and can be submitted to a collection facility nearby for disposal.
- The device and accessories may also be disposed of via ASSKEA GmbH or the service partner.
- Outside of the EU: See national disposal requirements!

8 Technical data

8.1 ASSKEA pro*cuff*® M

Flow rate* (measuring point at suction tube nozzle)	max. 8 l/min (low flow)
Vacuum	-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 step connector, Ø 4 mm (internal), length 150 cm
Nominal voltage of the power supply unit	In: AC 100 – 240 V~ / 50 – 60 Hz / 580– 320 mA Out: DC 12 V / 2,0 A
Maximum load current	2,0 A
Permissible input voltage	12 V
Power consumption at 12 V	24 W
Degree of protection pursuant to IEC 60601-1	Typ BF
Risk classification pursuant to 93/42/EEC, IX	IIa
Protection class pursuant to IEC 60601-1	II
IP degree of protection	IP33
CE marking	CE0494
UL-marking	E355754
Sound emission	Operation: 35 dB (A) High priority alarm: 53 dB (A) Low priority alarm: 52 dB (A)
Ambient conditions	*Transport / Storage* ambient temperature: -25 °C to +60 °C relative humidity: up to 93%, non condensing air pressure: 700 hPa to 1060 hPa
	Operation ambient temperature: +5 °C to +40 °C relative humidity: 15% to 93%, non condensing air pressure: 825 hPa to 1060 hPa
Battery	7,4 V; 4400 mAh (lithium-ion battery)
Charging time, if battery is empty	6 – 7 h
Energy battery pack	<80 Wh
Power supply unit	ATM024T-W120V
Dimensions basic device (H x W x D)	165 mm x 220 mm x 90 mm
Weight (basic device)	1.2 kg
Pressure display accuracy	Target pressure > -120 mbar max. Δ 5 % Target pressure ≤ -120 mbar max. Δ 10 %
Operating time	Continuous operation
Runtime in battery operation	approx. 18 h, depending on the strain of the motor
Expected service life	5 years
Item number (REF)	100710-3

* The information provided may differ depending on the altitude above sea level, the prevailing air pressure and the air temperature.

8.2 ASKEA procuff® S

Flow rate* (measuring point at suction tube nozzle)	max. 8 l/min (low flow)
Vacuum	-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 l)
Suction tube	PVCnoDEHP - suction tube with step connector, Ø 4 mm (internal), length 150 cm
Nominal voltage of the power supply unit	In: AC 100 – 240 V~ / 50 – 60 Hz / 580 – 320 mA Out: DC 12 V / 2,0 A
Maximum load current	2,0 A
Permissible input voltage	12 V
Power consumption at 12 V	24 W
Degree of protection pursuant to IEC 60601-1	Typ BF
Risk classification pursuant to 93/42/EEC, IX	IIa
Protection class pursuant to IEC 60601-1	II
IP degree of protection	IP33
CE marking	CE0494
UL-marking	E355754
Sound emission	Operation: 35 dB (A) High priority alarm: 58 dB (A) Low priority alarm: 56 dB (A)
Ambient conditions	*Transport / Storage* ambient temperature: -25 °C to +60 °C relative humidity: up to 93%, non condensing air pressure: 700 hPa to 1060 hPa
	Operation ambient temperature: +5 °C to +40 °C relative humidity: 15% to 93%, non condensing air pressure: 825 hPa to 1060 hPa
Battery rechargeable	7,4 V; 4400 mAh (lithium-ion battery)
Charging time, if battery is empty	6 – 7 h
Energy battery pack	<80 Wh
Power supply unit	ATM024T-W120V
Dimensions basic device (H x W x D)	290 mm x 259 mm (canister: + 100 mm) x 130 mm
Weight (basic device)	2.2 kg
Pressure display accuracy	Target pressure > -120 mbar max. Δ 5 % Target pressure ≤ -120 mbar max. Δ 10 %
Operating time	Continuous operation
Runtime in battery operation	approx. 18 h, depending on the strain of the motor
Expected service life	5 years
Item number (REF)	100707-3

* The information provided may differ depending on the altitude above sea level, the prevailing air pressure and the air temperature.

9 EMC information

WARNING: The use of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** directly adjacent to or stacked with other devices should be avoided, since this could lead to impermissible operation. If the use of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** adjacent to or stacked with other devices is required, the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** and the other devices should be monitored in order to verify proper operation in this arrangement!

WARNING: The use of accessories and spare parts, transformers and cables for the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** not indicated or provided by ASSKEA GmbH may increase the electromagnetic emissions or reduce the electromagnetic immunity of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**, resulting in impermissible operation.
No warranty is provided for damages caused by using accessories and spare parts, transformers and cables not recommended or by improper use.
Only use original **ASSKEA** accessories and spare parts!

WARNING: The use of the indicated or provided accessories and spare parts, transformers and cables for devices other than the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** may increase the electromagnetic emissions or reduce the electromagnetic immunity. No warranty is provided for damages caused by using the indicated or provided accessories and spare parts, transformers and cables with other devices or by improper use. Only use the accessories and spare parts, transformers and cables with the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**!

WARNING: Portable and mobile RF communication equipment (incl. peripheral devices such as antenna cables and external antennas) may influence medical electrical devices and therefore should not be used within a range of 30 cm of any part of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** incl. its cables. Otherwise the performance of the device may be impaired.

WARNING: The **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** may influence other devices, examinations and treatments electromagnetically. For this reason, special attention should always be paid to other devices and examinations or treatments performed in parallel so that any influence is detected as soon as possible.

The **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** devices meet the requirements of IEC 60601-1-2/EN 60601-1-2 “Electromagnetic Compatibility – Medical Electrical Equipment”, without deviations or restrictions. Therefore electromagnetic interference is reduced to a minimum. Follow the indicated instructions and guidelines to sustain the basic safety and the essential functions of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** over its entire expected service life.

9.1 Electromagnetic environment in which the devices may be operated

The **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** is intended for operation in the electromagnetic environment specified below, in which RF disturbances are controlled. The customer or the user of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** must ensure that it is operated in such an environment.
The environments for intended operation include professional healthcare institutions and the homecare environment. Special environments, such as close to RF surgery or MRI or environments, in which the intensity of EMC disturbances is high, are excluded.

Emission limits	
Conducted and radiated RF emissions	CISPR 11

Housing		
Phenomenon	**Test method**	**Immunity test levels**
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±15 kV air
Radiated RF disturbances	IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz
Radiated RF disturbances	pursuant to frequencies and immunity test levels of EN 60601-1-2, table 9	see EN 60601-1-2, Table 9
Magnetic field at rated power frequency (50 Hz)	IEC 61000-4-8	30 A/m

Power supply AC		
Phenomenon	**Test method**	**Immunity test levels**
Fast transient electrical disturbances/bursts	IEC 61000-4-4	±2 kV 100 kHz repetition frequency
Impulse voltages/surges	IEC 61000-4-5	±1 kV line-to-line ±2 kV line-to-ground
Conducted RF disturbances	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % U_T for ½ period At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % U_T for 1 period 70 % U_T for 25 periods one-phase at 0°
Voltage interruptions	IEC 61000-4-11	0 % U_T for 250 cycles
Note: U_T is the AC mains voltage prior to the application of the test levels.		

9.2 Handling of electromagnetic interactions

Although electromagnetic interference of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** has been reduced to a minimum, electromagnetic disturbances between the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** and other devices cannot be excluded. You should therefore always comply with the specified requirements and instructions regarding the permissible electromagnetic environment and monitor the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** in order to ensure proper operation and to prevent adverse events for patients and users. Select another location for the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**, if the permissible electromagnetic environment cannot be ensured or if you have observed functioning of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** or of another device in the vicinity that is not intended.

Since electromagnetic propagation is affected by absorption and reflection from structures, objects and people and since the field strength from fixed transmitters cannot be predicted in advance with accuracy, a site survey of the electromagnetic phenomena at the location at which the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** is going to be operated, should be considered to assess the existing electromagnetic environment at this location. If unusual performance is detected, additional measures may be required, for example a modified orientation or relocation of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S**. If the essential functions of the **ASSKEA pro*cuff*® M resp. ASSKEA pro*cuff*® S** are impaired by electromagnetic disturbances, a reduced or non-existent flow rate and vacuum may be expected.

9.3 Overview of all cables and transformers replaceable by the user

Name	Specification	Maximum length
Power supply unit	Type: ATM024T-W120V Technical data: 100-240 V~, 50-60 Hz, 580 – 320 mA (in) 12 V DC, 2,0 A (out)	4.0 m

10 Order information

10.1 ASSKEA pro*cuff*® M

Item number	Description	PU
100419	power supply unit ATM024T-W120V (incl. country adapters)	1
100790	disposable secretion canister (250 ml) with step connector	35
100705-2	variable holder prowound M, procuff M, ped M	1
100571	bag prowound M, procuff M, ped M	1

10.2 ASSKEA pro*cuff*® S

Item number	Description	PU
100419	power supply unit ATM024T-W120V (incl. country adapters)	1
100000	external canister “Bag” (1 l)	1
100002	disposable liner “OneWay” (1 l)	60
100267	holder external canister “Bag”	1
100013	exchangeable set double filter system (DFS®)	1
100280	connecting tube disposable secretion canister system	1
100663	disposable secretion canister,. suction tube, step connector	1
100295	bag for ASSKEA aspirators	1
100712	suction tube with funnel, connector and clamp, sterile	10

11 Publishing information

Created and published by:

ASSKEA GmbH
Haßlocher Strasse 9
99189 Gebesee
GERMANY

Contact details:

Telephone:	+49-36201-5797-0
Fax:	+49-36201-5797-33
E-Mail:	info@asskea.de
	www.asskea.de