Instructions for Use
ASSKEA ped M and ASSKEA ped S

CE 0494

GA14-15 / Revision K / 2024-01

The safety of the **ASSKEA ped M and the ASSKEA ped S** complies with the acknowledged rules of technology and meets the requirements of the **German Medical Devices Act**.
The **ASSKEA ped M and the ASSKEA ped S** devices 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, as well as with Article 120 of Regulation (EU) 2017/745 of the European Parliament and of the Council.
The **ASSKEA ped M and the ASSKEA ped 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 ped M and the ASSKEA ped S** are medical aspirators 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 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 accompanying documents, which contribute to improving the product, service or documentation.

Tell us what you are thinking about. For this, use one of the following opportunities:

- ➔ by email to mps@asskea.de
- ➔ by phone at +49 (0) 36201-5797-0
- ➔ by feedback survey at our homepage:
  https://asskea.de/wp-content/uploads/FB357-user-questionaire-PMS.pdf
  or scan the QR code to go directly to the questionnaire

2 User information

2.1 Using these instructions for use

Please read these instructions for use carefully before operating the **ASSKEA ped M or the ASSKEA ped S** devices for the first time.

Please read the safety instructions (Section 2.6) to avoid hazards.
These instructions for use are a component of the **ASSKEA ped M or the ASSKEA ped S**. Keep these instructions for use in an easily accessible place.
Include these instructions for use when passing the **ASSKEA ped M or the ASSKEA ped 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
	Filter run time elapsed; replacement of internal filter by service personnel is required!

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 ped 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 ped M and ASSKEA ped S** devices 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. Processing may only be performed by ASSKEA GmbH or by a service partner authorized by ASSKEA GmbH.

2.5 Purpose

2.5.1 Intended use

The **ASSKEA ped M and the ASSKEA ped S** are network-independent mobile medical aspirators for temporary and primarily spontaneous aspiration of aspirate from the trachea. The **ASSKEA ped M and the ASSKEA ped S** are especially designed for secretion aspiration in children and can be used in outpatient and inpatient care (professional healthcare facility environment).

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

- Tracheostomy patients
- Aspiration if respiratory function is impaired
- Aspiration of blood, secretion and food residues from the oral cavity, the pharyngeal zone and the bronchial system

2.5.5 Contraindications

The **ASSKEA ped M and the ASSKEA ped S** are contraindicated for the following applications:

- Liposuction
- Gynecology applications
- Dental applications
- Thoracic drainage
- Continuous drainage
- Applications in wound areas
- 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
- In the homecare sector

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 ped M or the ASSKEA ped 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 ped M or the ASSKEA ped S** (see section 8).

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 suitable sterile disposable catheter. The suction tube must never come into direct contact with the aspiration area.
- Follow the hygiene, cleaning and decontamination instructions.

Risk to persons due to strangulation

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

Risk of damage due to electromagnetic phenomena

Medical electrical devices are 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).

Damage to the device caused by ingress of liquids

The **ASSKEA ped M and the ASSKEA ped S** devices 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.
- Never submerge the device in water or other liquids (including while it is switched off).

Contact of the inner of the device with liquids or solids

If the inner of the device gets in direct contact with liquids or solids the device has to be proofed by the ASSKEA GmbH or an authorized distribution partner of ASSKEA GmbH.

Risk to persons due to improper handling

- Only use the devices for their intended purpose.
- Never use the devices for aspiration in the low vacuum range (e.g. thoracic drainage).
- If aspiration procedures are carried out too often, slight bleeding may occur.
- When using the power supply unit, ensure that it is first connected to the aspirator 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 aspirator).

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

Damage to the device caused by heat

- Do not cover the power supply unit.
- Keep the aspirators, the mains cable and the power supply unit away from other heat sources.

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 all components that are subject to wear and damage, to ensure that these 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)!

Possible physiological effects and unobvious risks

- To avoid personal injury, select the suction power depending on the respective patient and the medical indication.
- Always place the device 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 device. 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 device, 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**.**

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 ped M or the ASSKEA ped S** or by improper use.
Only connect recommended original parts with the **ASSKEA ped M or the ASSKEA ped S**.

2.7 User requirements

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

Training on how to handle the **ASSKEA ped M or the ASSKEA ped S** is provided by ASSKEA GmbH or an authorized distribution partner of ASSKEA GmbH. Product training 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 instructions for use,
- the device is opened by unauthorized personnel,
- the security seal is removed / broken,
- installation, settings, enhancements, routine maintenance, processings 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.

3 Product description

3.1 Overall view of the ME system

3.1.1 Asskea ped M

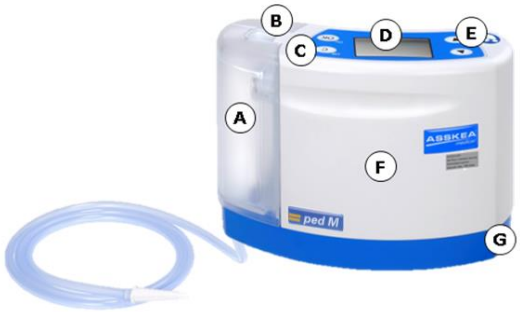


Fig. 1

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

Fig. 2

3.1.2 ASSKEA ped S with disposable secretion canister system

Fig. 3

A External canister “Bag” and and disposable liner “OneWay” (1 l)
B Holder for external canister “Bag”
C Connecting tube
D Display
E Control panel
((OK) (On) and (C) (Off) buttons and (▲) (Up) and (▼) (Down) arrow buttons)
F **ASSEKA ped S** device
G Socket for power supply unit

3.1.3 ASSKEA ped S with reusable secretion canister system

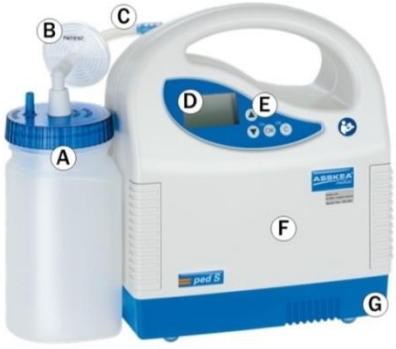


Fig. 3-1

A Secretion canister (reusable) with integrated overflow protection in the lid (see Fig. 18)
B Bacterial filter (external)
C Connecting tube
D Display
E Control panel
(OK (On) and C (Off) buttons and ▲ (Up) and ▼ (Down) arrow buttons)
F **ASSEKA ped S** device
G Socket for power supply unit

3.2 Scope of delivery

3.2.1 Scope of delivery ASSKEA ped M

- the **ASSEKA ped M** device
- 2 x disposable secretion canister with integrated bacterial filter, carbon filter, solidifier and suction tube
- power supply unit incl. country adapter
- these instructions for use
- multilingual charging instructions
- “Used Medical Device” label and decontamination certificate
- test report according to IEC 62353
- optional accessories (depending on the order)

3.2.2 Scope of delivery ASSKEA ped S with disposable secretion canister system

- the **ASSKEA ped S** device
- disposable secretion canister system

(comprising the external canister “Bag”, disposable liner “OneWay”, holder for external canister “Bag”, connecting tube and disposable suction tube)

- power supply unit incl. country adapter
- these instructions for use
- multilingual charging instructions
- “Used Medical Device” label and decontamination certificate
- test report according to IEC 62353
- optional accessories (depending on the order)

3.2.3 Scope of delivery ASSKEA ped S with reusable secretion canister system

- the **ASSKEA ped S** device
- reusable secretion canister system

(comprising the reusable secretion canister, S6 lid with ball for overflow protection, bacterial filter, connecting tube, tube mount and disposable suction tube)

- these instructions for use
- multilingual charging instructions
- "Used Medical Device" label and decontamination certificate
- test report according to IEC 62353
- optional accessories (depending on the order)

3.3 Product properties

The **ASSKEA ped M and the ASSKEA ped S** devices are lightweight, portable, battery-powered aspirators for inpatient and mobile use. The **ASSKEA ped M and the ASSKEA ped S** are especially designed for secretion aspiration in children and can be used in outpatient and inpatient care (professional healthcare facility environment).

The **ASSKEA ped M or the ASSKEA ped S** have a max. flow rate of 8 l/min
(see Section 8 "Technical data").

The **ASSKEA ped M or the ASSKEA ped S** are operated via the internal battery or via the supplied power supply unit, which can also be used to recharge the battery. 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 secretion canister system, which is used to aspirate fluids (via a suitable sterile suction catheter). The aspirate is directed away from the patient and collected in the secretion canister.

If the secretion canister is full, the device triggers an alarm via an integrated overflow protection and stops the pump. The **ASSKEA ped M** device must only be operated with the supplied disposable secretion canister. The **ASSKEA ped S** device can be operated with the supplied disposable secretion canister system as well as with the reusable secretion canister system, which is also available.

The provided disposable secretion canister for the **ASSKEA ped M** as well as the disposable liner "OneWay" and the suction tube for the **ASSKEA ped S** are intended for single use.

3.3.1 Disposable secretion canister for the ASSKEA ped M

The disposable secretion canister consists of a canister with a connected suction tube. The disposable secretion canister has an integrated bacterial filter, carbon filter and solidifier. The hydrophobic bacterial filter integrated in the disposable secretion canister is effective against bacteria and viruses. This integrated filter prevents an overflow in the event of an operational error or a full canister. 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 odor.

Solidifier:
Disposable secretion canisters filled with aspirate can be transported and disposed of in a leak-proof manner by using the solidifier and closing the tube clamp. 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. 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 ped M

The filter system of the **ASSKEA ped 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 filter installed in the disposable secretion canister, is effective against bacteria and viruses.

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

Service life and reuse

The internal filter of the ASSKEA filter system 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 on 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

An additional filter in the exhaust air vent of the **ASSKEA ped M** and the **ASSKEA ped S** neutralizes 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 odor.

Service life and reuse

The carbon filter of the **ASSKEA ped M** and the **ASSKEA ped S** 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 Secretion canister system for the ASSKEA ped S

Disposable secretion canister system:
The disposable secretion canister system consists of the external canister “Bag”, the holder for the external canister “Bag”, the disposable liner “OneWay”, the connecting tube and the suction tube. The disposable liner “OneWay” has an integrated bacterial filter, carbon filter and solidifier. The self-sealing bacterial filter integrated in the disposable liner “OneWay” is effective against bacteria and viruses. This integrated filter prevents an overflow in the event of an operational error. If the liquid reaches this filter, aspiration is no longer possible and the error message “System closed – canister full” appears on the display. The aspiration process is 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” and the suction tube if it is full, prior to each new patient or weekly at the latest, in accordance with applicable hygiene instructions.

Reusable secretion canister system:
The reusable secretion canister system consists of a reusable secretion canister, a canister lid with integrated overflow protection, a suction tube and a connecting tube with external bacterial filter. The external bacterial filter is effective against bacteria and viruses. It 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 external bacterial filter must be replaced.

The **reusable secretion canister** is intended for **multiple use**. Replace the external bacterial filter in accordance with applicable hygiene instructions, prior to each new patient and also in the event of discoloration, contamination or reduced suction power.

3.3.5 Information on the double filter system for the ASSKEA ped S

The ASSKEA double filter system DFS® consists of the external bacterial filter integrated in the disposable liner "OneWay" and the external bacterial filter of the reusable secretion canister system installed in the device. The filters are self-sealing bacterial filters which, in combination, are effective against bacteria and viruses.

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

Service life and reuse

The ASSKEA double filter system DFS® is 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 on 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

The charge level of the battery is shown on the display.
It is strongly recommended to fully charge the battery prior to first startup of the **ASSKEA ped M and the ASSKEA ped S** devices and to repeat this after the first uses.

The **ASSKEA ped M and the ASSKEA ped S** devices 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).

The battery of the **ASSKEA ped M and the ASSKEA ped S** devices are protected against deep discharging. The battery is also protected against overheating during charging. If the battery temperature is exceeded during charging due to improper ambient conditions, charging is temporarily discontinued to allow cooling. The purpose of this measure is to ensure safe operation and to protect the battery.

The typical service life of the battery is approx. 300 load cycles, subsequently more than 80 % of the primary capacity is still available.

3.3.7 Pressure settings

Once the **ASSKEA ped M or the ASSKEA ped 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 -350 mbar (in steps of 5 mbar). The setting of the pressure values is described in Section 4.3.1.

Always use the lowest possible pressure setting. Adjustments to device settings must only be made if instructed to do so and only by healthcare professionals. Prior to switching on the **ASSKEA ped M or the ASSKEA ped S**, it must be ensured that the devices are equipped with the corresponding secretion canister.

3.4 Warranty

Modifications of the ME device are not permitted.

The **ASSKEA ped M and the ASSKEA ped 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,
- processing and repair are performed by professionals authorized by ASSKEA GmbH or by ASSKEA GmbH itself,
- the **ASSKEA ped M and the ASSKEA ped S** are used and operated in accordance with the instructions for use and for their intended use.

All warranty claims shall be void, if:

- the device is opened by unauthorized personnel,
- the security 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

- Please read Sections 4.1 and 4.2 carefully!
- The **ASSKEA ped M and the ASSKEA ped S** may only be operated and used by instructed and appropriately trained personnel.
- Use only suitable suction equipment!
- If aspiration procedures are carried out too often, slight bleeding may occur.

Malfunction due to aspirated aspirate

- Empty the reusable secretion canister when it is half-full to curtail frothing. If the reusable secretion canister is full, the mechanical overflow protection is triggered. This disrupts the aspiration process and the alarm “System closed – canister full” is activated.
- Ensure that the disposable secretion canister of the **ASSKEA ped M** and the disposable liner “OneWay” of the **ASSKEA ped S** are replaced on a regular basis. If the disposable secretion canister or the disposable liner “OneWay” is full, the integrated overflow protection 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” or when emptying the reusable secretion canister.
- If aspirate has been aspirated into the device, it must be properly processed by ASSKEA GmbH or by an authorized service partner of ASSKEA GmbH!

Damage to the device due to insufficient acclimatization

After the device has been exposed to ambient temperatures outside of the technical data (see Section 8) during transport / storage, it must first acclimatize for approx. 2 hours 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 ped M or the ASSKEA ped S**:

4.1.1 Connection of the ASSKEA ped M and the ASSKEA ped S

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

Use the socket for the power supply unit of the **ASSKEA ped M** (Section 3.1.1, Fig. 1/2(G)) or the socket for the power supply unit of the **ASSKEA ped S** (Section 3.1.2 / 3.1.3, Fig. 3/3-1(G)) to connect the device to the mains power supply via the supplied power supply unit 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 the power supply unit of the **ASSKEA ped M or the ASSKEA ped S** and then to the mains power supply.

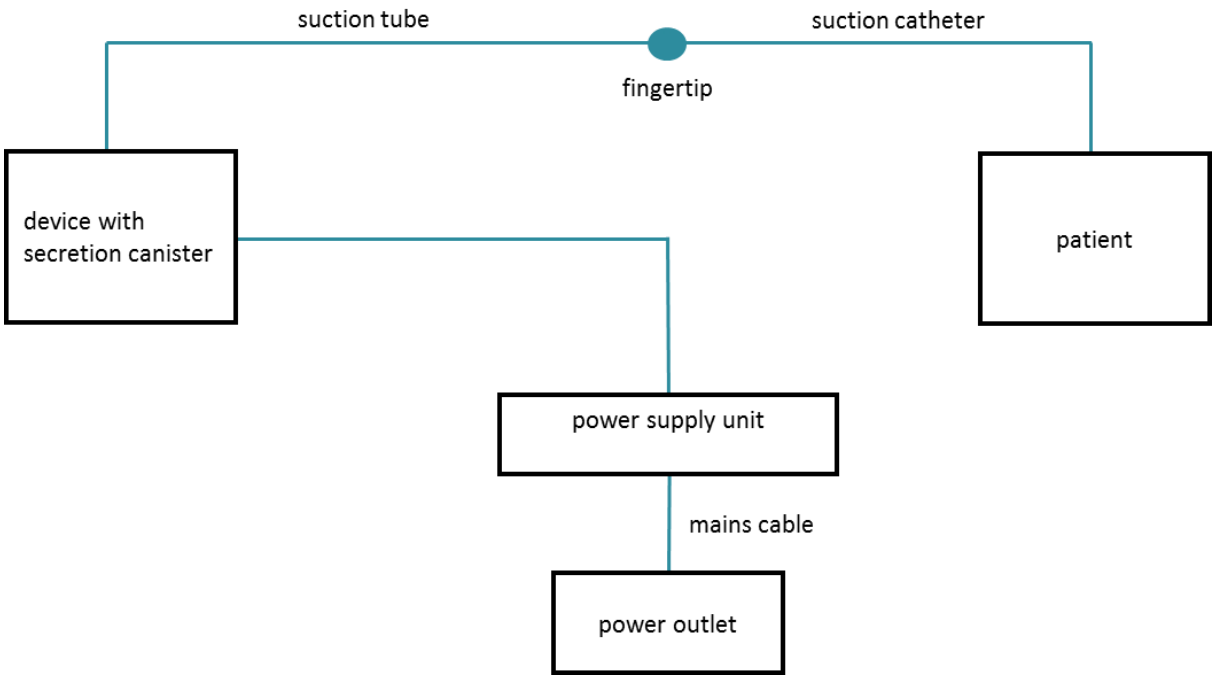


Fig. 4 Connection of the ASSKEA ped M or the ASSKEA ped S to the patient and accessories

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 ped M** and a backup disposable liner “OneWay“ (1 l) for the **ASSKEA ped S** ready, since these are essential for safe operation!

- Please read these instructions for use carefully before operating the **ASSKEA ped M or the ASSKEA ped S** devices for the first time.
- Remove the device and the accessories from the packaging.
- Always place the device on a sturdy, flat surface. Ensure the device is positioned correctly.
- Inspect all tubing as well as the power supply unit for damage prior to each startup of the **ASSKEA ped M or the ASSKEA ped S**.
  It is important to avoid kinking when connecting the tubing. Prior to switching on the unit, ensure that the secretion canister and the tubing are properly connected.
- Fully charge the battery prior to initial startup.
- Perform a function test! (See Section 6.1)

4.2.1 Positioning of the ASSEKA ped M

The **ASSKEA ped 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. It is, however, up to the physician to decide whether the condition of the patient permits portable use. The **ASSKEA ped M** with a 250 ml canister can also be used in a horizontal position according to the following figure:

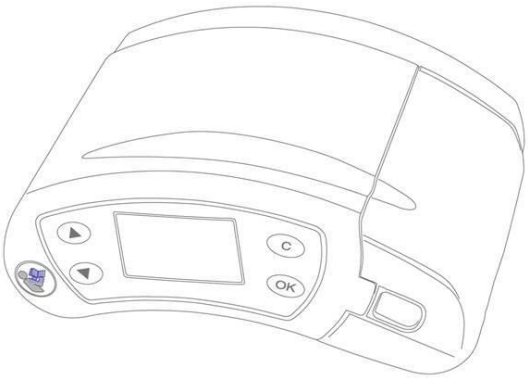


Fig. 5 ASSKEA ped M used horizontally

To ensure optimum aspiration, place the **ASSKEA ped M** below the patient to be treated. It should be noted that the suction tube does not form a dip and is situated at least at patient level.

4.2.2 Connection of the disposable secretion canister of the ASSKEA ped M

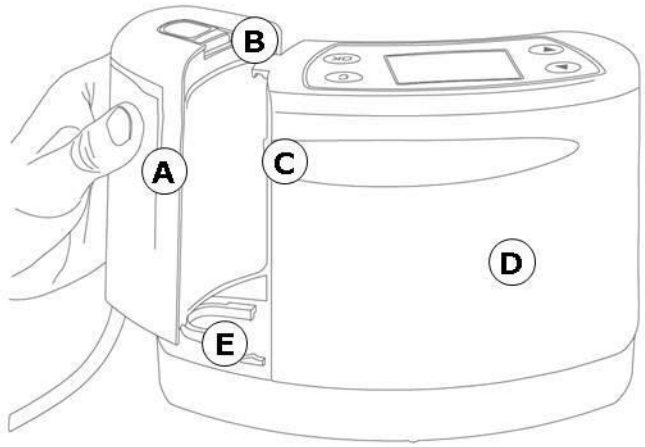


Fig. 6 Connection of the disposable secretion canister

A Disposable secretion canister incl. suction tube
B Canister locking mechanism
C Aspiration port
D **ASSKEA ped M**
E Guide rail for canister

1. Remove the disposable secretion canister (Fig. 6 (A)) from the packaging.
2. Slide the canister onto the guide rail (Fig. 6 (E)) of the **ASSKEA ped M** until the disposable secretion canister clicks into place in the locking mechanism (Fig. 6 (B)).

4.2.3 Positioning of the ASSKEA ped S

The **ASSKEA ped 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, place the **ASSKEA ped S** below the patient to be treated. It should be noted that the suction tube does not form a dip and is situated at least at patient level.

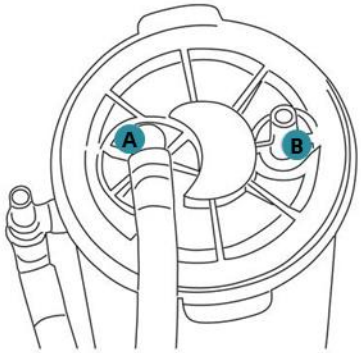
4.2.4 Connection of the disposable secretion canister system of the ASSKEA ped S

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 disposable suction tube with step connector.



Connection designation:

A Vacuum connection
B Patient connection

Fig. 7

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

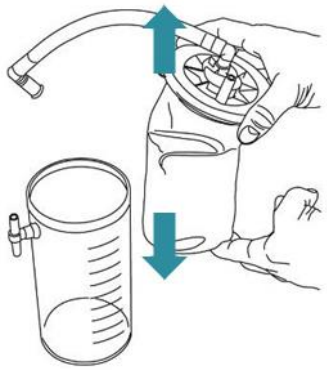


Fig. 8

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

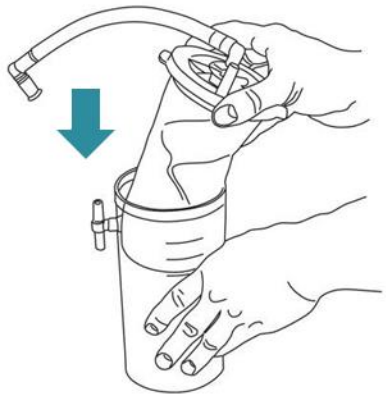


Fig. 9

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

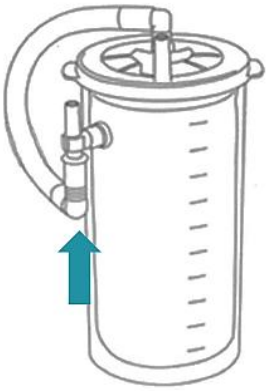


Fig. 10

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.

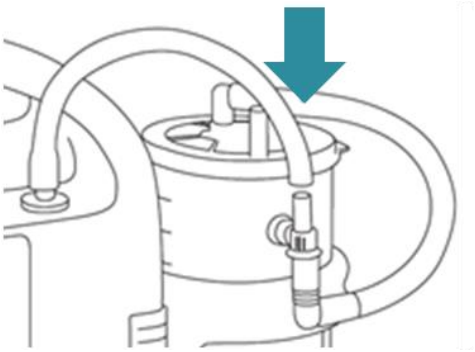


Fig. 11

5. Connect the patient connection of the disposable liner “OneWay” (Fig. 6 (B)) to the suction tube. Ensure that the tube is fixed sufficiently tightly.

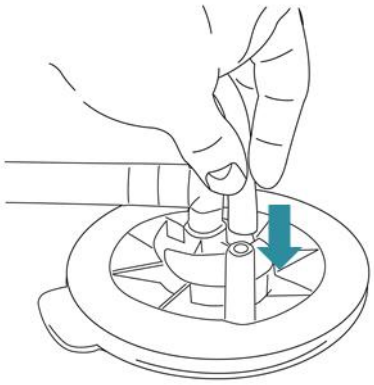


Fig. 12

4.2.5 Connection of the reusable secretion canister system of the ASSKEA ped S

1. Screw the lid of the reusable secretion canister sufficiently tightly and attach the canister to the device.

2. Insert the connecting tube with the blue elbow fitting to the side of the device. Ensure that the side of the external bacterial filter marked “Patient” is facing the canister (directed toward the patient)!

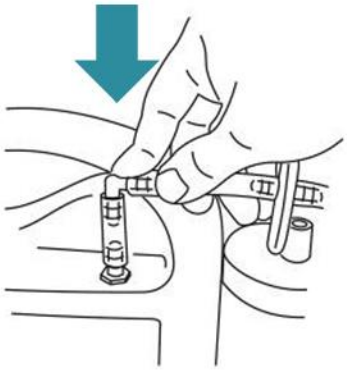


Fig. 13

3. Place the gray elbow adapter of the connecting tube onto the connection in the middle of the secretion canister lid (above the overflow protection).

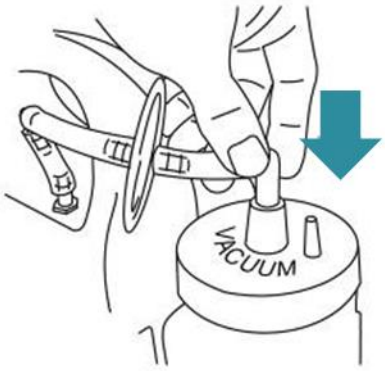


Fig. 14

4. Place the suction tube onto the second connection (patient connection). Ensure that the tube is fixed sufficiently tightly.

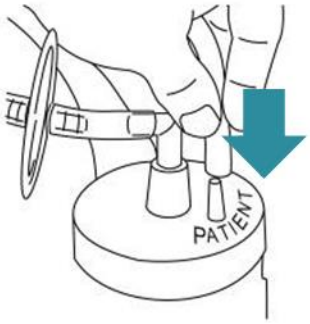


Fig. 15

The reusable secretion canister or the holder for the external canister “Bag” is attached by directly sliding it onto the guiding rails on the housing of the device (Figs. 16, 17).

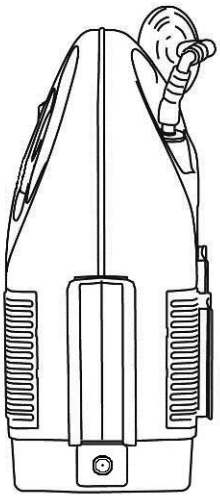


Fig. 16

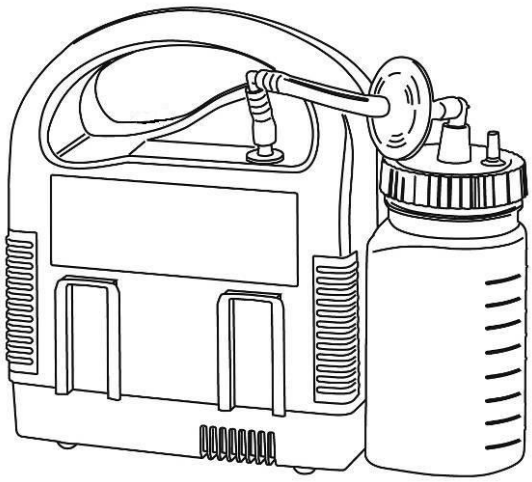


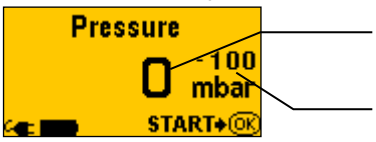
Fig. 17

4.3 Operation of the ASSKEA ped M and the ASSKEA ped S

4.3.1 Operation at startup

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

2. After 5 seconds, the following screen is displayed. Two values are shown. (preset of the target value: -100 mbar)



Actual value

Target

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

4. Press the OK button to start the pump.

5. Press the OK button to stop the pump.

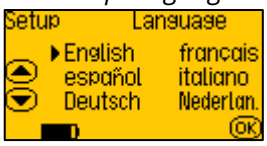
6. Switch off the **ASSKEA ped M or the ASSKEA ped S** by pressing the C button for 3 seconds.

4.3.2 Language selection

German is the default language for the **ASSKEA ped M and the ASSKEA ped S** devices. To customize the language, follow these steps:

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

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



3. Use the ▲ ▼ arrow buttons to select the desired language.

4. Use the OK button to confirm your choice.

4.4 Patient mode

The **ASSKEA ped M or the ASSKEA ped S** enable the selection of patient mode at startup. In patient mode, the patient runtime can be viewed and reset.
To select patient mode, follow these steps:

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

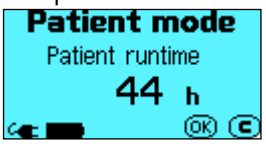
2. While the start screen is displayed, press and hold down the C button and additionally press the OK button for 1-2 seconds. The *Authorization* screen is displayed.

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. Training as well as the authorization code can be obtained from ASSKEA GmbH or an authorized service partner of ASSKEA GmbH.

Passwords must be treated as confidential information to prevent misuse.

4. The patient runtime is displayed.



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

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

4.5 Canister replacement

Note the hints for health risks due to the handling of infectious or pathogenic germs in Section 5.1.1.

4.5.1 Replacement of the disposable canister of the ASSKEA ped M

1. Switch off the **ASSKEA ped M**.
2. Close the tubing clamp on the suction tube.
3. Remove the suction tube from the suction catheter.
4. Press on the locking mechanism at the top of the canister (Fig. 6 (B)) and keep it pressed while pulling the disposable secretion canister horizontally away from the device.
5. Dispose of the disposable secretion canister and the integrated suction tube in a properly manner (see Section 7.3 “Disposal”).
6. Attach a new disposable secretion canister to the device. Ensure that the disposable secretion canister is properly connected to the device.
7. Connect the suction tube to the suction catheter.
8. Switch on the **ASSKEA ped M**.

4.5.2 Replacement of the disposable liner “OneWay” of the ASSKEA ped S

1. Switch off the **ASSKEA ped S**.
2. Close the tubing clamp on the suction tube.
3. Remove the suction tube from the suction catheter.
4. Remove the pre-assembled connecting tube of the disposable liner “OneWay” at the bottom end of the T-piece of the external canister “Bag” and the suction tube from the patient connection on the lid of the disposable liner “OneWay”.
5. Remove the disposable liner “OneWay” from the reusable external canister “Bag”.
6. Dispose of the disposable liner “OneWay” in a properly manner (see Section 7.3 “Disposal”).
7. Insert a new disposable liner “OneWay” into the reusable external canister “Bag” as specified in Section 4.2.4. Ensure that the connecting tube and the lid of the disposable liner are properly seated on the external canister.
8. Attach the suction tube to the patient connection of the disposable liner “OneWay” and connect it to the suction catheter.
9. Switch on the **ASSKEA ped S**.

If the **ASSKEA ped S** is used in combination with the reusable secretion canister system, please follow the instructions regarding cleaning / disinfection in Section 5.1.7.

4.6 Decommissioning

Note the hints for Health risks due to the handling of infectious or pathogenic germs in Section 5.1.1.

1. Switch off the device after the aspiration by pressing the ⏻ button 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 ped M or the ASSKEA ped S**.
3. Remove the disposable secretion canister of the **ASSKEA ped M** as described in Section 4.5.1 up to and including point 5.
4. Remove the disposable liner “OneWay” of the **ASSKEA ped 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. If you are using the **ASSKEA ped S** with the reusable secretion canister system, firstly remove the suction tube from the suction catheter and from the secretion canister. Pull the reusable secretion canister off the guide rails on the device and subsequently follow the instructions for cleaning and disposal of the components of the reusable secretion canister system in Sections 5.1.7 and 5.1.8.
5. Clean the surface of the device according to Section 5.1.2.
6. Store the device in the shipping carton until the next use.

5 Maintenance

5.1 Cleaning and 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 components that have come into contact with the aspirate.
- Use the disposable secretion canister or the disposable liner “OneWay” for one patient only.
- Replace the disposable secretion canister incl. suction tube (**ASSKEA ped M**) or the disposable liner “OneWay” (**ASSKEA ped S** with disposable secretion canister system) if it is full, prior to each new patient or weekly at the latest, in accordance with applicable hygiene instructions.
- Replace the external bacterial filter prior to each new patient or in the event of discoloration, contamination or reduced suction power (**ASSKEA ped S** with reusable secretion canister system).
- Replace the disposable suction tube of the **ASSKEA ped S** according to the respective applicable hygiene regulations, at the latest weekly and in case of patient change.
- For each new patient, professional hygienic 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.

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 device.
- 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 ped M or the ASSKEA ped S**

Damage to the device due to improper cleaning agents

- Do not use acetone-based disinfectants and solvent-based cleaning agents. 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 “Sekusept® aktiv” for immersion disinfection of the accessories and “Incidin® Liquid” for wipe disinfection of the device.

5.1.2 Cleaning / 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-down disinfection.

Frequent 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.

5.1.3 Disposal of the disposable secretion canister of the ASSKEA ped 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 (see Section 7.3).

5.1.4 Disposal of the disposable liner “OneWay” and the suction tube of the ASSKEA ped S

1. Close the tubing clamp on the suction tube.
2. Remove 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 external canister “Bag”.
4. Dispose of the disposable liner “OneWay” and the suction tube in a proper manner (see Section 7.3).

5.1.5 Cleaning / disinfection of the external canister “Bag” of the ASSKEA ped 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. Then 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.

ASSKEA GmbH recommends replacing the external canister “Bag” after 30 autoclaving processes at the latest, in the event of visible damage or functional restrictions, if it is used and disinfected frequently or for each new patient.

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.

Frequent 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 device.

ASSKEA GmbH recommends replacing the holder for the external canister “Bag” for each new patient.

5.1.7 Cleaning / disinfection of the reusable secretion canister system of the ASSKEA ped S

A Reusable secretion canister lid
B Overflow protection
C Ball (for overflow protection)
D Reusable secretion canister

Fig. 18

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

1. Empty the reusable secretion canister and dispose of the aspirate in a proper manner.
2. Remove the ball (overflow protection) before performing the following cleaning instructions (Fig. 18(C)) and clean or disinfect it separately.
3. Rinse all components of the reusable secretion canister system under running water.
4. Immerse all components of the reusable secretion canister system in disinfectant solution, in accordance with the specific concentration quantity. The reusable secretion canister system can also be autoclaved at 121 °C for 20 minutes with the exception of the ball.
5. Then rinse the components thoroughly and allow them to dry. When using an appropriate cleaner manufactured by DR. WEIGERT (e.g. “neodisher AN”), cleaning in a special dishwasher is also possible, in accordance with the manufacturer’s instructions.
6. Assemble the dry components according to Fig. 18.

ASSKEA GmbH recommends replacing the reusable secretion canister after 30 autoclaving processes at the latest or in the event of visible damage or functional restrictions, if it is used and disinfected frequently. In accordance with hygiene regulations, the reusable secretion canister must be replaced when the patient is changed.

5.1.8 Cleaning / disinfection of the tubing accessories of the ASSKEA ped S

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

1. Remove the external bacterial filter of the reusable secretion canister system and dispose of it in a proper manner prior to cleaning the connecting tube.
2. Rinse the connecting tube with clear water and place it in the disinfectant solution recommended by ASSKEA GmbH for immersion disinfection.
3. Then rinse the connecting tube with clear water and allow it to dry!

In accordance with applicable hygiene instructions, ASSKEA GmbH recommends replacing the connecting tube **every 4 weeks** at the latest.

5.2 Processing / Reuse of the device

The **ASSKEA ped M or the ASSKEA ped S** is 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 ped M or the ASSKEA ped 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!

6 Troubleshooting

6.1 Function test

Perform a function test of the device without the connected canister prior to use in therapy. Proceed as follows:

1. Switch on the device as described in Section 4.3.
2. Start the therapy and allow the device to idle. The alarm “System open” must appear after 60 seconds at the latest. However, if the alarm “Syst. closed – canister full” appears instead, the internal filter of the **ASSKEA ped M or the ASSKEA ped S** is blocked and should be replaced by service personnel.
3. Acknowledge the alarm by pressing OK.
4. Then 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.

Also perform a visual inspection before each use of the device. Also include accessories for this purpose.

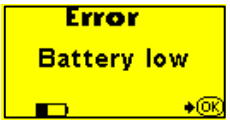
6.2 Troubleshooting

Malfunction	Probable causes	Remedy
Device cannot be switched on.	Battery is empty.	Connect the power supply unit.
	Display foil is defective.	Please contact a service partner!
No aspiration possible / no flow of aspirate	Suction tube blocked / kinked.	• Rinse / change the suction tube. • Adjust the position of the device. • Verify proper connection of the tubing.
	Tubing clamp is closed.	Open the tubing clamp.
	Disposable secretion canister is full.	Replace the disposable secretion canister (for **ASSKEA ped M**).
	Overflow protection is blocked.	Empty the reusable secretion canister (for **ASSKEA ped S**).
	Disposable liner “OneWay” is full.	Replace the disposable liner “OneWay” (for **ASSKEA ped S**).
	External bacterial filter is blocked.	Replace the external bacterial filter (for **ASSKEA ped S** with reusable secretion canister system).
	Internal filter is blocked.	Please contact a service partner!

Contact 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 acknowledged by pressing the OK button.
- Alarm messages of high priority are shown on 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 on 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 is full (for **ASSKEA ped M**).	Replace the disposable secretion canister (for **ASSKEA ped M**).
		Disposable liner “OneWay” or reusable secretion canister is full (for **ASSKEA ped S**).	Replace the disposable liner “OneWay” or empty the reusable secretion canister (for **ASSKEA ped S**).
		External bacterial filter is blocked (for **ASSKEA ped S** with reusable secretion canister system).	Replace the external bacterial filter (for **ASSKEA ped S** with reusable secretion canister system).
		Flow of aspirate is disripted (tube kinked or stenosis in the tube).	Check the tubes for kinks.
		If the alarm is displayed even if the canister is not connected, the internal bacterial filter is blocked.	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!
	Current operating mode continues to run in the background.	Low battery charge level.	Connect the power supply unit.
	(Alarm after 15 minutes) Back-up mode continues to run in the background.	The therapy was not started.	Start the therapy.
		The device was not switched off.	Switch off the device.

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

7 Transport, storage and disposal

7.1 Transport / Return

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

The **ASSKEA ped M and the ASSKEA ped S** devices must be cleaned and disinfected prior to shipment to ASSKEA GmbH. Please follow the instructions set out in Section 5.1.2! All disposable products are to be disposed of. Power cable and power supply unit are to be enclosed for examination of the return shipment. Please affix the supplied “Used Medical Device” label to the original shipping carton! Please give ASSKEA GmbH advance notice of your product return. The product return form is available in the “Service” area of our website (www.asskea.de) under “Product return”.

7.2 Storage

Store the **ASSKEA ped M and the ASSKEA ped S** devices as indicated in the technical data (Section 8)!

The battery of the **ASSKEA ped M and the ASSKEA ped S** aspirators 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 ped M and the ASSKEA ped S** devices are 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 ped M

Flow rate* (measuring point at suction tube nozzle)	max. 8 l/min (low flow)
Vacuum	-60 mbar to -350 mbar (in steps of 5 mbar) (medium vacuum) Conversion factor: 1 kPa ~ 7.5 mmHg; 1 kPa ~ 10 mbar
Canister	Disposable secretion canister
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	Type BF
Risk classification pursuant to 93/42/EEC, IX	IIa
Protection class pursuant to IEC 60601-1	II
International Protection	IP33
CE marking	CE0494
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, rechargeable	min. 7.2 V; lithium ion battery
Charging time if battery is empty	6 – 7 h
Energy of 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 %
Runtime in network operation	Continuous operation
Runtime in battery operation	approx. 18 h, depending on the strain of the motor
Expected service life	5 years
Item number (REF)	100567-3-EW (with disposable secretion canister system)

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

8.2 ASSKEA ped S

Flow rate* (measuring point at suction tube nozzle)	max. 8 l/min (low flow)
Vacuum	-60 mbar to -350 mbar (in steps of 5 mbar) (medium vacuum) Conversion factor: 1 kPa ~ 7.5 mmHg; 1 kPa ~ 10 mbar
Canister	Disposable secretion canister system (1 l); Reusable secretion canister system (1 l)
Suction tube	Disposable suction tube with step connector, Ø 4 mm (internal), length: 180 cm (REF: 100712-1)
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	Type BF
Risk classification pursuant to 93/42/EEC, IX	IIa
Protection class pursuant to IEC 60601-1	II
International Protection	IP33
CE marking	CE0494
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	min. 7.2 V; lithium ion battery
Charging time if battery is empty	6 – 7 h
Energy of 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 %
Runtime in network operation	Continuous operation
Runtime in battery operation	approx. 10-20 h, depending on the strain of the motor
Expected service life	5 years
Item number (REF)	100566-3-EW (with disposable secretion canister system) 100566-3-MW (with reusable secretion canister system)

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

9 Electromagnetic compatibility

The devices **ASSKEA ped M and ASSKEA ped S** were teste according to EN 60601-1-2:2015 and correspond to the limit values.
These limits and test leves are designed to provide reasonable assurance of immunity to electromagnetic interference when the equipment is used in its intended environment. For more information on electromagnetic immunity and electromagnetic radiation, please contact the ASSKEA GmbH at info@asskea.de or download it from ASSKEA GmbH website at www.asskea.de/download.

10 Order information

10.1 ASSKEA ped M

Item number	Description	PU
100790	disposable secretion canister (250 ml) with step connector	35
100705-2	variable holder for prowound M, procuff M ped M,	1
100571	bag prowound M, procuff M, ped M	1

10.2 ASSKEA ped S

Item number	Description	PU
Disposable secretion canister system		
100663	disposable canister system, suction tube, step connector	1
100000	external canister “Bag” (1 l)	1
100002	disposable liner “OneWay” (1 l)	60
100267	holder external canister “Bag”	1
100280	connecting tube disposable secretion canister system	1
100712-1	suction tube with funnel, connector and clamp	10
Reusable secretion canister system		
100279	reusable secretion canister (1 l)	1
100205	lid S6 for reusable secretion canister	1
100283	tube mount (holding ring with tube clamp)	1
400512	external bacterial filter	5
100712-1	suction tube with funnel, connector and clamp	10
Other accessories		
400503	exchangeable set double filter system (DFS®)	1
100282	rinsing bottle (250 ml)	1
100295	bag for ASSKEA aspirators	1

11 Publishing information

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