ATMOS
MedizinTechnik
... for a better life

English

Operating instructions

ATMOS C 161 Battery

313.0400.B
OM.01

CE 0124

Table of contents

Further information, accessories, consumables and spare parts are available from:

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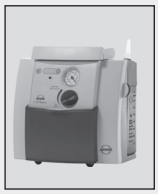
1.0 Introduction

1.1 Notes on operating instructions



These operating instructions contain important notes on how to operate the ATMOS C 161 Battery safely, correctly and effectively. Their reading helps to avoid risks, and also to reduce repair costs and down-time. That increases, amongst other things, the reliability and service-life of the device. These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual.

These operating instructions must always be kept available near the device.

Care and safety inspections in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS C 161 Battery and are therefore a must besides regular cleaning.

Repair work and safety inspections may be carried out only by expert personnel authorised by ATMOS. By applying only original spare parts you will have the guarantee that operational safety, readiness for work and the value of your ATMOS C 161 Battery will be preserved..

- The product ATMOS C 161 Battery bears CE marking according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of annex I of this directive.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 9001 and EN ISO 13485.
- Prior to start-up please peruse chapter 2.0 „For your safety“, in order to be prepared for any possible dangerous situations.
- These operating instructions correspond to the design of the ATMOS C 161 Battery and the status of basic safety engineering standards on going to press.
- Reproduction of these instructions – even in part – only with the written permission of ATMOS.
- Subject to alterations and changes.

These operating instructions are valid for the following devices:

- ATMOS C 161 Battery DDS REF 313.0400.0
  with 1l DDS grad. secretion container
- ATMOS C 161 Battery Receptal® REF 313.0401.0
  with 1l Receptal® container
- ATMOS C 161 Battery Medi-Vac® REF 313.0402.0
  with 1l Medi-Vac container

In combination with the accessories mentioned in chapter 11.0 as well as for all identically constructed devices with special voltage.

Please store this document near the device for later use!

1.0 Introduction

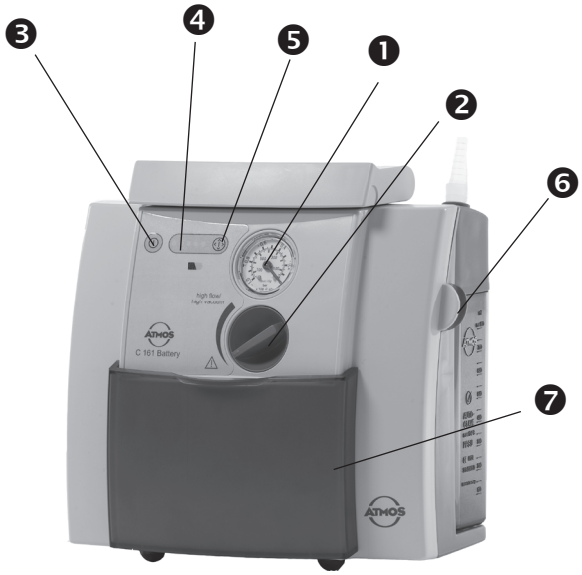


fig 1.

ATMOS C 161 Battery / DDS

1. Vacuum gauge
2. Vacuum control
3. On/off push button
4. Charge level indicator
5. Battery test button
6. Hose holder
7. Sliding cover for protecting the control elements

1.2 Function

The ATMOS C 161 Battery is a very handy small suction unit. It is driven by an electromotive, maintenance-free diaphragm-type pump. During operation, the pump generates a vacuum within the hose system and the collection jar, thus sucking off secretions or fluids (e.g. by means of a suction catheter). The fluid is gathered in the collection jar. A mechanical overflow safety (on the inner part of the collection jar lid) avoids penetration of secretion into the pump head. The final vacuum and, following, the air-flow rate can be adjusted by means of the fine control and the vacuum-gauge. The unit is equipped with a rechargeable battery (accu-mulator). Integrated microprocessor-based technology assures safe charging of the battery; overcharging is thus impossible. An overtemperature stop controlled by electronics avoids overheating of the unit. A disposable bacterial filter plate integrated in the lid of the collection jar prevents bacteria and liquid from penetrating into the pump.

For ATMOS C 161 Battery / DDS:

The reusable secretion container is connected to the pump housing via direct-docking, without any pedestrian hose system. Only the suction hose has to be plugged in by the user.

A bacterial filter, located in the lid of the secretion container, avoids entering of bacterias and liquids into the pump interior. A mechanical oversuction stop integrated in the container lid additionally avoids accidentally absorbtion of secretion into the pump head.

1.3 Intended use

- The ATMOS C 161 Battery s in battery-operated medical suction device for temporary and spontaneous suction of secretions and body fluids, which typically occure with airway suction.

The fields of application are:

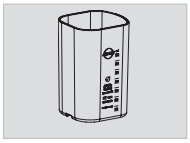
- in-patient and out-patient care, for secretion suction (sputum), body fluids and rinsing liquids.
- in geriatric nursing for secretion suction (sputum), body fluids and rinsing liquids as well as for spontaneous suction of foreign bodies, for example, after a foreign body aspiration.
- in home care for bronchial toilet on laryngectomy and tracheo-tomy patients (with tracheal cannula). Especially for aspiration of mucus, sputum, secretion and body fluids in tracheostoma patients.

- **The ATMOS C 161 Battery may *not* be used:**
  - **for drainages in low vacuum ranges (e.g. for thorax drainage)**
  - **for suction procedures outside medical ranges (for the suction of inflammable, corrosive or explosive fluids/gases)**

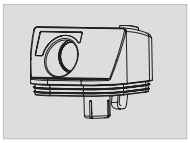
1.4 Scope of supply

- Prior to dispatch, this ATMOS device was subjected to an extensive functional test and has been carefully packed. Nevertheless, please compare the contents of the shipment on completeness immediately upon receipt (see delivery note). In addition to the basic device, the scope of delivery comprises the following parts:

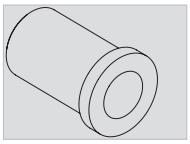
ATMOS C 161 Battery / DDS



Grad. secretion container (1l)

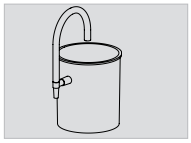


Lid for secretion container with triple oversuction safety

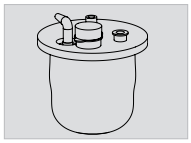


2 DDS bacterial filter

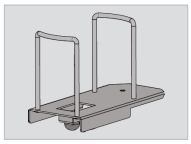
ATMOS C 161 Battery / M



MediVac container (1l)

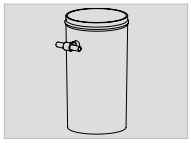


MediVac suction bag (1l)

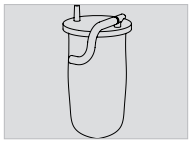


Support

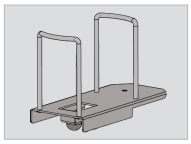
ATMOS C 161 Battery / R



Receptal® containter (1l)

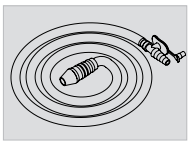


Receptal® suction bag (1l)

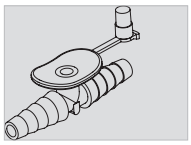


Support

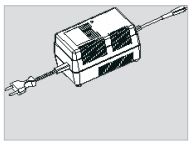
ATMOS C 161 Battery, scope of supply of all versions:



Silicone suction hose Ø 6mm, L= 1,30m



Hose connector (fingertip)



Battery charging power pack

1.5 Transport and storage

- The transport of the device may be effected only in a dispatch carton upholstered and offering sufficient protection.
- Please document and report damages in transit immediately. For complaints or return deliveries, please use the enclosed form **QD 434**.
- The unit must be allowed to stand for up to six hours at room temperature prior to starting up for the first time following transport at temperatures below freezing. The unit may **not** be operated if it has **not** acclimatised as this might damage its diaphragms.
- Ambient conditions:

Transport/Storage:	-30...+50°C; 5...90 % air humidity non-condensing at air pressure 700...1060 hPa
Operation and battery charging:	+10...+35°C; 20...80 % air humidity non-condensing at air pressure 700...1060 hPa

1.6 Explanation of symbols

Important information!	Application part type BF	The CE sign shows that this product meets the appropriate requirements of the EC guidelines.
Warning, especial diligent notice !	**SN** Serial number	Pump On/off
Protection class II	**REF** Order number	Battery test function (only ATMOS)
Fuse	Manufacturing date	

2.0 For your safety

General safety information

- Prior to starting up the ATMOS C 161 Battery, read these operating instructions carefully.
- ATMOS cannot guarantee perfect functioning neither will it be liable for damage to people or property if:
  - Any non-original ATMOS parts are used,
  - the user instructions given in this manual are not followed exactly or are disregarded,
  - Assembly, resetting, alterations, extensions and repairs are not carried out by people authorised by ATMOS.
- In the case the pump is switched on, while a high vacuum (>40 %) is applied, the device switches off automatically (safe condition). The charge level indicator for the battery is blinking. Switch on is only possible after ventilation of the vacuum.
- No warranty rights shall exist in the event of damage or failure caused by the use of non-ATMOS accessories or non-ATMOS consumables
- Use transparent hoses only.
- The safety standard of the ATMOS C 161 Battery corresponds with recognized medical technical regulations and the directions of the law relating to medical products.
- The electrical outlet is in fact carried out three-pole, but the middle contact pin (normally ground wire connection) in the interior of the unit is **not** connected.

Danger of injury!

- Only persons instructed in medical use may apply the ATMOSC 161 Battery to patients.
- The ATMOS C161 has been designed for aspirating body fluids in medical ranges. Never remove explosive gases and inflammable or corrosive fluids.
- Sterile packed parts may no longer be used if their packing was damaged during transport or storage ⇨ Danger of infection for the patient.
- The unit may not be operated in splash water range and in locations where there is a danger of explosion (zones M and G).
- The suction hose must never come into direct contact with the application site.
  Always use a sterile suction catheter resp. a medical accredited aspiration set.
- This suction unit may not be applied without disposable bacterial filter plate.
- In order to disconnect the device from the mains, please remove the plug of the battery charging power pack from the wall socket.
  - Prior to cleaning and servicing the device.
  - Before emptying the secretion container.
- During storage of the device continuous recharging with the charging unit is required in order to provide full performance in emergency cases.

Danger to the device

- Prior to operation, inspect the mains plug. Only operate the device when the mains plug is not damaged!
- The unit may not be started:
  - If cables or plugs are defective,
  - If it has been dropped down before,
  - If obvious defects might restrict safe operation.

  Clean the device prior to returning for repair.
- The unit may not be operated in splash water range and in locations where there is a danger of explosion (zones M and G).
- Pay attention to the ambient conditions described in chapter 1.5 Transport and storage.
- Never plunge the unit into water, not even when it is switched off.
- Do not allow any liquid to get into the unit. If liquid has penetrated the unit, it may not be operated again, until it has been checked by the customer service centre.
- The unit must be set up on a firm, level surface. The switched-on unit might get overheated if it is placed on an uneven surface (e.g. mattress, cushion, padded seat etc.).
- The main voltage specified on the type plate must match the power supply system.
- Never connect the unit to defective power sockets or extension cables.
  Avoid moisture on plug and switches.
- The unit, collection jar, mains cable, accessories, connection cables and hoses must be checked for damage prior to starting up. Damaged cables and hoses must be replaced immediately. **Prior to use, check the unit functions.**

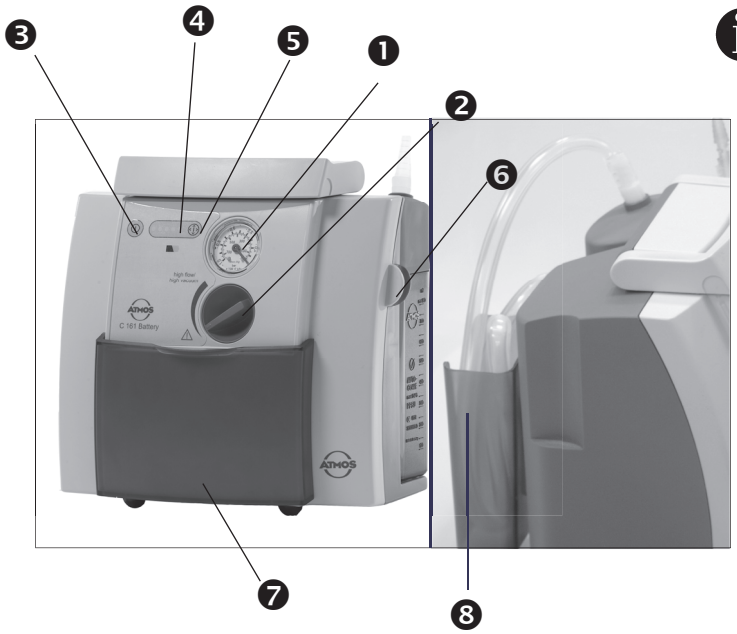


Fig 2.

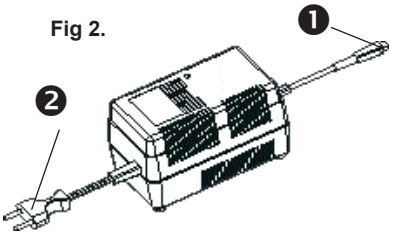
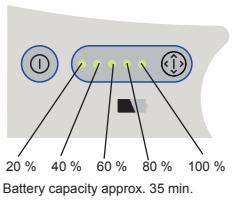


Fig 4.

Fig 3.



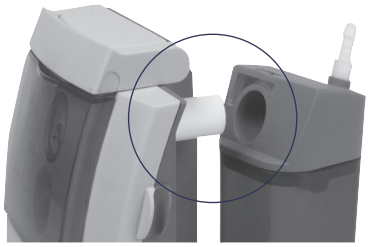


Fig 5.

3.0 Setting up

- Set up the device on a level, firm surface.

3.1 Operating elements

1. Vacuum gauge
2. Vacuum control
3. On/off push button
4. Charge level indicator
5. Battery test button
6. Hose holder
7. Sliding cover for protecting the control elements
8. Hose rewind (accessory)

3.2 Connection

The main voltage specified on the type plate must match the power supply system.

Check mains cable for damages. Damaged cables must be replaced immediately!

3.3 Starting up

- The ATMOS C 161 Battery is delivered ready for use.
- Lift the unit out of the cardboard. Check whether the voltage values on the data plate correspond with the inbuilding voltage.
- Set up the device on a level, firm surface.
- Prior to first operation, pay attention to the safety information in chapter 2.0.
- The unit must be allowed to stand for up to six hours at room temperature prior to starting up for the first time following transport at temperatures below freezing. The unit may **not** be operated if it has **not** acclimatised as this might damage its diaphragms.
- ATMOS C 161 Battery / DDS: Always hold ready at least one DDS bacterial filter, as the device cannot be operated without one!

3.4 Charging the battery

The battery is charged by the 12 V low voltage connector (fig. 4). Chapter 9.3 contains a reference to the battery handling.

3.4.1 Charging with battery charging power pack

Connect the low voltage connector (fig 4, 1) to the low voltage socket at the device. Connect the mains plug of the battery charging power pack (fig 4, 2) to the wall socket.

3.4.2 Charging with battery charger leads (12V)

Connect the low voltage connector to the cigarette lighter in the car.

With both methods, full suction capacity is available during charging. Even with fully discharged respectively defective batteries it is possible to operate the device via 12 V low voltage connection. The full suction capacity is available. In order to prevent the device from fully discharge it switches off automatically after approx. 10 minutes.

4.0 General operation ATMOS C 161 Battery

Prior to these notes please read the foregoing chapter of your respective version of the ATMOS C 161 Battery!

Important notes on safety

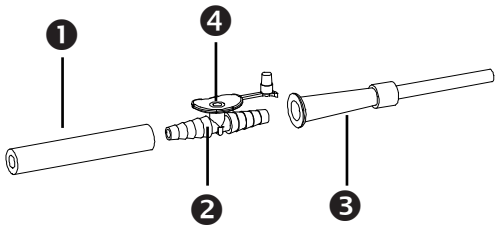
- Attention: Suction procedures in the respiratory tract may only be implemented after appropriate instruction by hospital or special staff.
- Make sure that the collection jar is evacuated in time. As soon as the jar is half-filled, it must be emptied (this principle proves right in all applicaton ranges).
- When the maximum level is exceeded, the overflow safety reacts and suction is stopped. Empty the jar
- Check the vacuum readout regularly!
- If secretion has been soaked up into the pump due to improper use or manipulation, the device must be repaired from a service patner authorised by ATMOS.
- For aspiration use only applicable suction catheters, attachments or a medical aspiration sets.
- Whilst aspirating please pay attention to the filling level of the secretion container.

4.1 Suction hose

- Join the suction hose (❶) and the suction catheter (❸) by means of the finger tip (❷).

4.2 Adjust vacuum

- Adjust your desired vacuum by closing the suction hose opening with the finger (❶) the vacuum is then generated. Open the regulating valve / vacuum control (page 4, ❷) until the vacuumgauge shows the desired vacuum value
- Choose a suction catheter of the right size (❸ which are available from ATMOS in 3 different sizes) or a suction instrument which is only available from specialized dealers.



❶ Suction hose
❷ Finger tip
❸ Suction catheter
❹ Auxiliary air vent

Fig 6.

AUXILIARY AIR VENT OPEN =
suction procedure is interrupted (e.g. when leading in the catheter)

AUXILIARY AIR VENT CLOSED WITH THE FINGER = suction

4.3 Suction procedure

- Then, lead in the catheter in the same way as shown by your hospital staff and start the suction procedure.
- Control the suction procedure with the auxiliary air vent (❹) on the fingertip.
- The hydrophobic DDS bacterial filter / oversuction stop safely avoids ingress of moisture. Nevertheless you should empty the jar at a fill level of 1/2.
- The secretion container system is designed the way that secretions flows laterally to the wall. Therefore the foam formation in the container is reduced.

4.4 Hose rinsing

- Dispose the suction catheter and rinse the suction tube with clean water or disinfection liquid after every suction procedure. We recommend to use the rinsing bottle in which you can carry clean water along with you. A separate rinsing container set is avaible (REF 313.0008.0).

5.0 Operation ATMOS C 161 Battery / DDS

Important
notes on safety
for the DDS jar system

- **The device cannot be operated without DDS bacterial filter / oversuction stop! Therefore always hold ready a replacement DDS bacterial filter!**
- Before each use, check that the DDS bacteria filter / oversuction stop is clean and dry. Wet or dirty filters must be replaced with new ones. The filter is no longer in optimum condition if the vacuum displayed is above -0.3 bar when the vacuum controller is in the ”max.” position and the suction hose is open. The filter must then be replaced.
- Please use gloves when changing the bacterial filter!
- The DDS bacterial filter / oversuction stop is disposable.
  Therefore the DDS bacterial filter must be changed each time the device is used by another patient.
  In the case the device is exclusively used in **one** patient, the filter must be exchanged at least every two weeks. (depending on frequency of use)
- **Vacuum connection Direct-Docking-System**
  The vacuum connection between the pump and the collection jar is created automatically as soon as the DDS jar is positioned correctly.

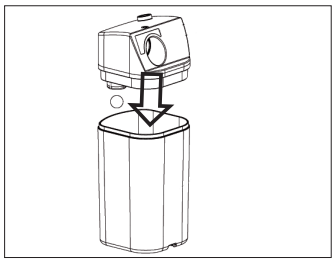
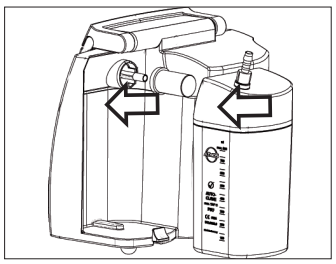


Fig 7.

5.1 DDS container and DDS bacterial filter

- With the DDS collection jar on a firm surface, position the lid horizontally on top (the lid may not be twisted!)
- Press down lightly onto the collection jar using both hands until limit is reached (Fig 7).



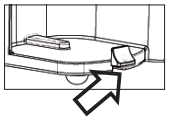


Fig 8.

5.2 Insertion of the DDS container

- For removal, pull the DDS collection jar horizontally outside; for insert it again, shift it horizontally onto the bacterial filter (Fig 8.).

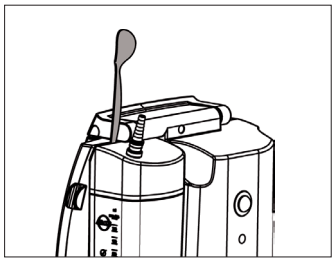


Fig 9.

Tip

If required the container can be ejected even easier from the device by means of a lever instrument (e.g. plain spattle); see Fig. 9.
For further easement of the container ejection, the sliding property can be increased by applying e.g. vaseline on the junction lid/device.

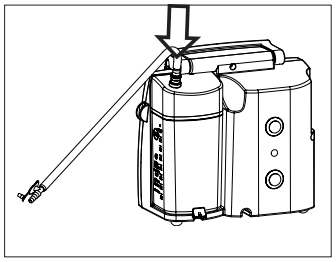


Fig 10.

5.3 Connect hose

- Press the required DDS hose adapter with 6 or 10 mm diameter into the hole of the DDS collection jar lid twisting slightly to ensure a tight fit (Fig 10).
- Twist slightly in the same manner when removing.

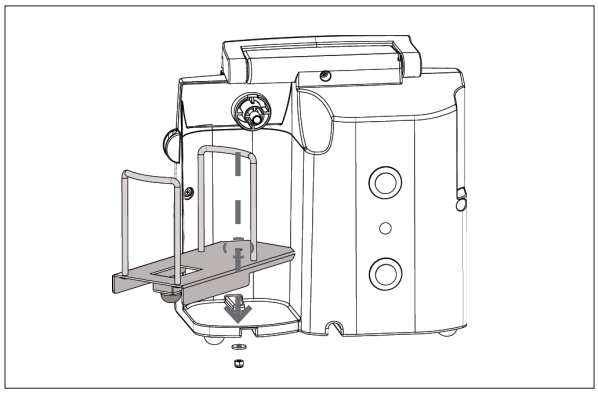


Fig. 11.

6.1 Holder for Receptal® secretion container

Plug the screw thread of the holder from the top into the borehole at the bottom side of the device.
Screw it together with the provided screw nut.

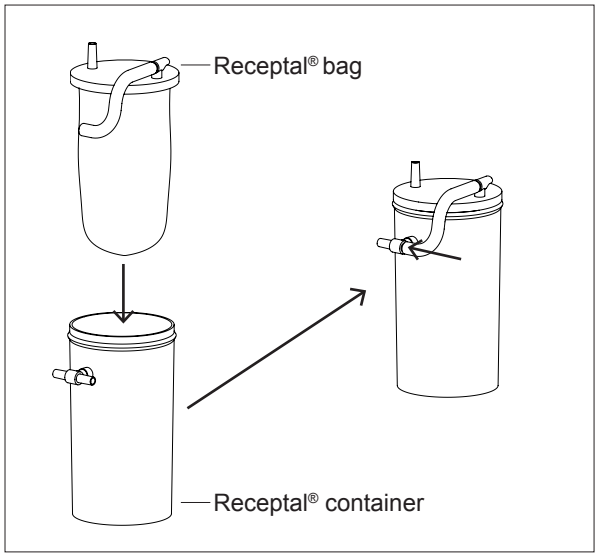


Fig 12.

6.2 Assembling the Receptal® secretion jar system

Insert the Receptal® bag into the Receptal® container.

Close the jar tightly at all sides.
Check again for density, otherwise no vacuum can be built up.

Insert the vacuum hose.

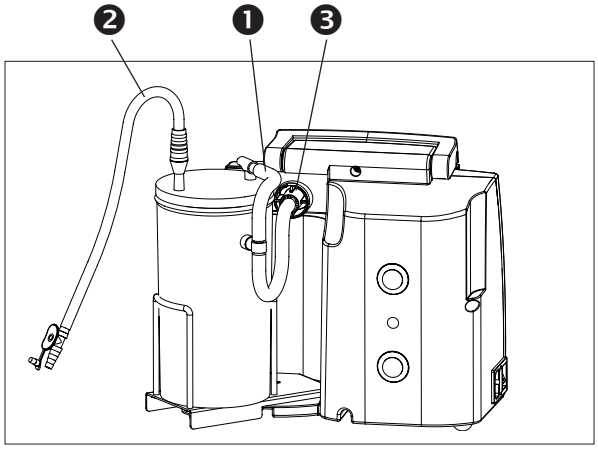


Fig. 13.

6.3 Connect hose

❶ Vacuum hose
❷ Vacuum channel
❸ Connection for vacuum hose

The secretion is sucked off through the vacuum channel.

- Sterile packed parts may no longer be used if their packing was damaged during transport or storage
  ⇨ Danger of infection for the patient.
- **Only use secretion bags with integrated bacterial filter!**
  A bacterial filter avoids divulgement of bacterias.

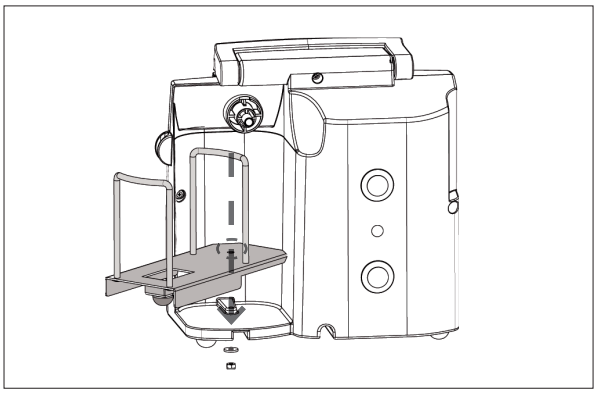


Fig. 14.

7.1 Holder for MediVac secretion container

Plug the screw thread of the holder from the top into the borehole at the bottom side of the device.
Screw it together with the provided screw nut.

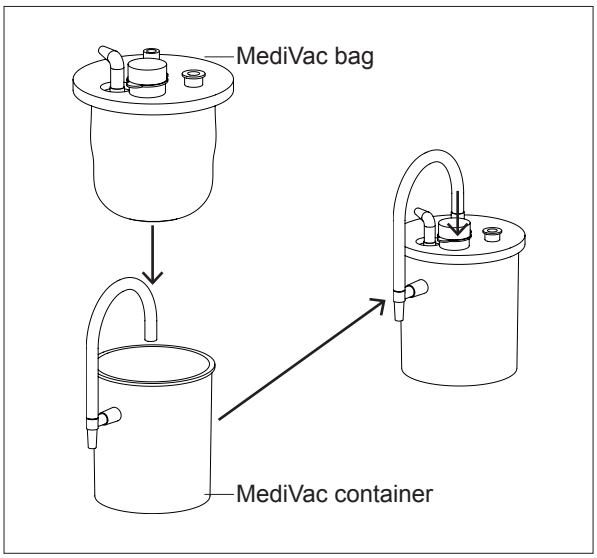


Fig.15.

7.2 Assembling the MediVac secretion jar system

Insert the MediVac® bag into the MediVac® container.

Close the jar tightly at all sides.
Check again for density, otherwise no vacuum can be built up.

Insert the vacuum hose.

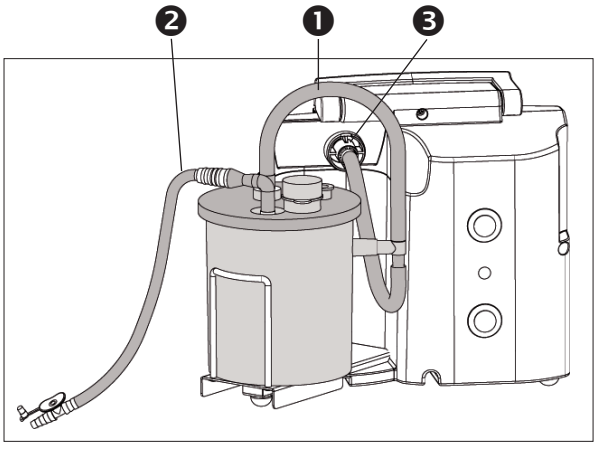


Fig.16.

7.3 Connect hose

❶ Vacuum hose
❷ Vacuum channel
❸ Connection for vacuum hose

8.1 Basic information

For ATMOS C 161 Battery DDS:

- **Change the bacterial filter!**

- **when being used by just one patient:**
  The filter must be exchanged at least every two weeks.
  (see chapter 8, enclosed cleaning and servicing plan)

- **when being used by *more* than one patient:**
  Change filter per person

- Remove the mains plug from the socket before starting cleaning and disinfection!
- The measures described for cleaning and disinfection or sterilisation are not intended to replace the regulations applicable for operation in each case!
- Always comply on principle with the relevant manufacturer's information regarding concentration and notes for use!
- **Attention:** The lid parts and silicone hoses might get dyed by some disinfectants; a fact which does not take effect on the attributes of the materials. These silicone and collection jar parts may also be boiled (for more than 10 min).
- Basically, all parts which come into contact with secretion must be cleaned, disinfected or sterilized after every use. Consumables like, e.g. filters, catheter,..., must be exchanged.
- **We recommend changing the hoses every 4 weeks!**
- Pay attention to storing a sufficient number of replacement bacterial filters! DDS bacterial filter oversuction stop are available in packaging units of 10, 50, and 100 pcs (REF 340.0054.0)

8.1.1 Cleaning the unit's surfaces

If liquid has penetrated the unit, it may not be operated again until it has been checked by the authorised customer service centre.

- The surfaces of the ATMOS C 161 Battery are resistant against all the surface disinfectants. Nevertheless after any length of time discolourations could possibly develop.
- The unit itself can be wiped off with a moist cloth (not wet).

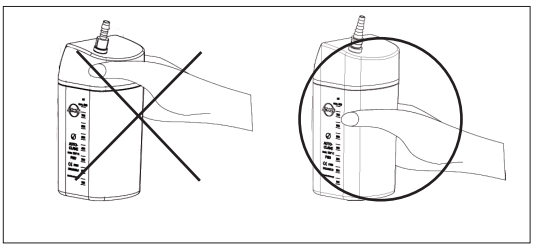


Fig. 17.

8.2 Empty the DDS secretion container

- Never carry or lift the container on the lid!
  Risk: Lid is loosening from the container.
- Pull the container out backwards.
- Lift-off the container lid.
- Empty container.
- Properly dispose of the sucked material.
- Pull out the suction hose and take the white swimming ball out of the integrated oversuction stop.
  Clean the container in a dishwasher, by hand or autoclave it.

8.2.1 Cleaning the container parts

- Collection jar and collection jar lid may be rinsed under running water or cleaned in an automatic cleaning device
- Silicone hoses and secretion container parts (container, lid, oversuction stop) can be autoclaved (up to 134°C). Likewise these parts can be inserted in standard disinfection liquids (see page 12).

  Using the cleaning agent Neodisher AN (manufactured by Dr. Weigert, Hamburg) cleaning in a special dishwasher is also possible. The disposable bacterial filter plate must be removed before cleaning.

Cycles of reprocessing

		autoclavable
Secretion container	313.0005.0	min. 1000x
Lid of secretion jar	313.0006.0	min. 100x
Silicone hose	000.0013.0	min. 20x
Rinsing container set	313.0008.0	min. 5x

8.3 Cleaning the rinsing container

- The rinsing container may only be cleaned with a ph neutral cleaning liquid which *does not* contain the following ingredients: ammoniac, amines, amides, phenol derivates, anionic tenides.
- The disinfection is exclusively allowed with alcohol-based disinfecting liquid. The may *not* contain the following ingredients: aromatic hydrocarbons, ammonia, amine (e.g. Pursept-A, Fa. Merz Hygiene)
- The rinsing container can be autoclaved at 134°C (min. 5 cycles)
- Cleaning in a dishwasher is possible when using ph neutral cleaning liquids (min. 5 cycles)
- Boiling2

8.4 Recommended disinfectants for instruments

Disinfectant	Contents	(in 100 g)	Manufacturer
GIGASEPT FF	Succindialdehyde	11.0 g	Schülke & Mayr, Norderstedt
(Application concentrate)	Dimethoxytetrahydrofurane	3.0 g	
	Corrosion inhibitors		
	Non-ionic tensides and fragrances		
Sekusept PLUS[1]	Glucoprotamine	25.0 g	Ecolab, Düsseldorf / not for rinsing container
(Application concentrate)	Non-ionic tensides		
	Solvents, complexing agents		
Mucozit-T	Bis(3-aminopropyl)laurylamine	8.0 %	Merz & Co., Frankfurt/Main
(Application concentrate)	Alkyl dimethylbenzyl ammonium chloride	19.0 %	
	Cocospropylendiamin-1,5-guanidiniumacetat	7.0 %	

8.5 Recommended disinfectants for surfaces

Disinfectant	Contents	(in 100 g)	Manufacturer
TERRALIN	Benzalkonium chloride	20.0 g	Schülke & Mayr, Norderstedt
(Application concentrate)	Phenoxypropanoles	35.0 g	
QUATOHEX	Didecyl dimethyl		Braun, Melsungen
(Application concentrate)	ammonium chloride	14.0 g	
	Benzalkonium chloride	10.0 g	
	Bi-guanidinium acetate	7.5 g	
	Polymer biguanide	0.5 g	
	Active cleaning substances		
Incidin Plus	Glucoprotamine	26.0 g	Ecolab, Düsseldorf / not for rinsing container
(Application concentrate)	Non-ionic tensides		
	Solvents, complexing agents		
Pursept-A	Ethanol	38.9 g	Merz & Co., Frankfurt/M.
(Disinfectant spray or	Glyoxal	0.1 g	
disinfectant cloths)	QAV	0.05 g	

Discolouration may result if disinfectants containing aldehydes and amines are used on the same object.

Cleaning and servicing plan for ATMOS C 161 Battery

start date:	name of the item:	serial number:

day	cleaning secretion containe-hälter	cleaning container lid	cleaning of the housing	exchange of bacterial filter	exchange of fingertip	exchange of suction hose, 1.3 m		cleaning/exchange performed	
								name	signature
				exchange*	exchange*	exchange*			
					exchange				
					exchange				
					exchange				
					exchange				
				exchange	exchange				
					exchange				
					exchange				
					exchange				
					exchange				

daily, respectively after each use

daily, respectively after each use

daily, respectively after each use

* Before first time operation of a brand new device, respectively a reprocessed device, an exchange is unnecessary!

Special notes:
Before operating the suction device, the user has to make sure that the device functions and is in good order and condition. The user has to observe the instructions in the operating manual as well as all other safety-related and maintenance information enclosed.

For cleaning and disinfection only agents which are recommended by the manufacturer, may be used.
Only sterile, single-use suction catheters may be used for suctioning. They have to be exchanged before each suction process. During use utmost attention to hygiene (e.g. disinfection of hands, wearing single-use gloves) is indispensable. After each use the secretion container and the hose must be rinsed thoroughly with water. During storage the contamination of the device and other products must be avoided. The intervals stated in the list are non-binding guide values. Depending on the use shorter intervals may be necessary.

For each patient a new or a reprocessed suction device must be used. Otherwise there is high and acute danger of infection for the patient, the user and any third person!

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ATMOS MedizinTechnik

Important notes

General information

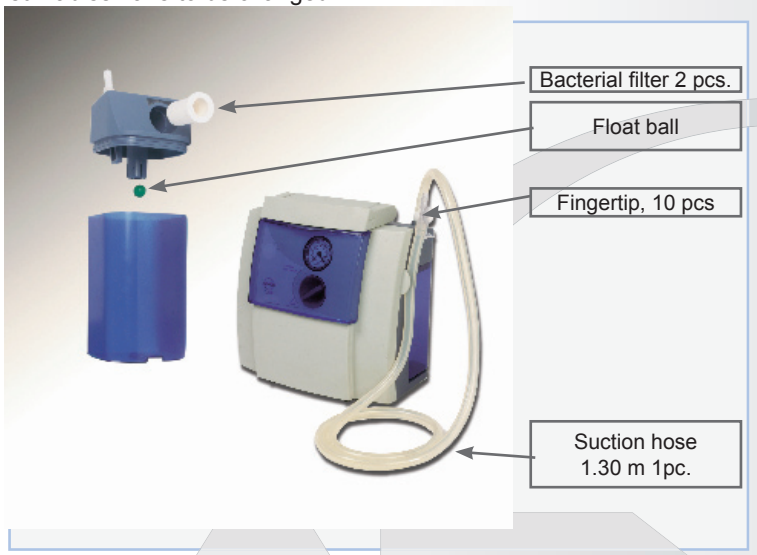
The way the suction device is used determines its reliability and safety. These hygiene measures are indispensable for protecting the patient and the user and for maintaining a safe and reliable suction device.

These measures do not replace a reprocessing, performed by the manufacturer or by any certified ATMOS partner before re-using the device on a new patient.

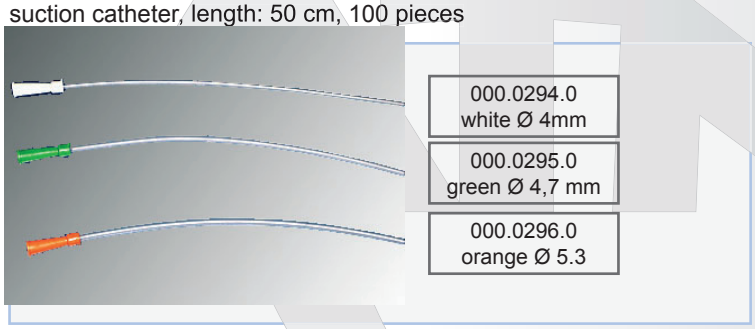
This cleaning and servicing plan as well as the relevant notes result from many years of experience. Depending on the use and the user's experience shorter intervals may be necessary.

ATMOS recommends the following sets of consumables:

According to this cleaning and servicing plan the following consumables have to be changed:



suction catheter, length: 50 cm, 100 pieces



☞ Disconnect the mains plug from the socket before commencing with cleaning and disinfection!

☞ Please observe the notes in the operating instructions, especially regarding the recommended agents.

☞ All parts (except bacterial filter and device, Sterile parts and consumables) are autoclave-safe up to 130°C.

Cleaning of the secretion container

Please empty the secretion container after each use, rinse it thoroughly with warm water and clean it with washing-up liquid. Tenacious

contaminations can be removed with a standard bottle brush.

Cleaning of the container lid

The bacterial filter must be removed before cleaning, please use single-use gloves or tweezers. Please demount the container lid after each use and rinse it thoroughly. The lid must be absolutely dry before reuse. Please pay attention to a correct function of the overflow safety when mounting the lid.

Bacterial filter

The bacterial filter prevents penetration of micro organisms and secretion into the device, respectively blowing out from it and is therefore a protection for the user and the device. For hygienic reasons a weekly exchange is recommended. If the maximum vacuum is adjusted, the suction hose is open and the vacuum gauge shows a basic vacuum of > -0.3 bar, then the bacterial filter must be exchanged immediately. In case of contamination the filter must also be replaced. In order to increase the service life of bacterial filters, it is recommended to empty the secretion container when it is half-full. Always use the original ATMOS bacterial filter

☞ The suction device cannot be operated without bacterial filter!

Hose connection/fingertip

The fingertip connects the suction hose to the suction catheter. As the fingertip is in direct contact with secretion, and it is difficult to clean, we recommend a daily exchanged.

Suction Hose

The suction hose conducts the secretion from the suction catheter to the container. In order to prevent secretion from drying, the hose must be thoroughly rinsed with clear water after each use. The water can be sucked into the secretion container. Please fill the secretion container only half. Frequent cleaning and disinfection/sterilisation may discolour and embrittle the hose. Therefore, a monthly exchange of the suction hose is recommended.

Cleaning of the device (housing)

When the device is contaminated but at least once per week the housing must be wiped off with a moist (but not wet) cloth. A weekly disinfection is recommended.

☞ Never irrigate the device with water and never emerge it into any liquid.

Cleaning/disinfection

To improve the cleaning effect, standard washing-up liquid can be added to the warm water. In the case of tenacious contamination the parts should be steeped in water for a length of time or they may be removed with a soft brush or cloth. After thorough cleaning, container, fingertip and hoses can be disinfected with a disinfection agent (see operating instructions). As an alternative the parts can also be boiled (except the device).

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9.0 Maintenance and servicing

9.1 Basic information

- Carry out a visual inspection of the unit prior to each use including hoses, collection jar and connection cable. **Damaged cables and hoses must be replaced immediately.**

- Maintenance or opening and repair of the ATMOS C 161 Battery (with the exception of the cleaning work described in these operating instructions) may only be carried out by ATMOS or a specialist authorised by ATMOS. In this case, attention should be paid to the protective technical and hygiene measures, the notes on safety plus the descriptions in the servicing instructions for the ATMOS C161.

- For repair, this device can be returned to ATMOS.

- Before returning the device for repair, clean and afterwards disinfect all secretion container parts and hose parts. The device´s surface also has to be disinfected.

- ATMOS cannot guarantee perfect functioning neither will it be liable for damage to people or property if:
  - Any non-original ATMOS parts are used,
  - the user instructions given in this manual are not followed exactly or are disregarded,
  - assembly, resetting, alterations, extensions and repairs are not carried out by people authorised by ATMOS.

- No warranty rights shall exist in the event of damage or failure caused by the use of non-ATMOS accessories or non-ATMOS consumables.

- In order to protect the user, the ATMOS C 161 Battery must be reprocessed prior to passing on. Reprocessing may only be performed by ATMOS or a specialist who is authorised by ATMOS. Furthermore it must be performed in line with MPBetreibV, MPG and BV-Medrules.

- Pay attention to regulations and instructions valid for the respective application range.

9.2 Reprocessing

The way the suction device is used determines its reliability and safety. These hygiene measures described in the last chapter are indispensable for protecting the patient and the user and for maintaining a safe and reliable suction device.

These measures are no substitute for a reprocessing of the device by the manufacturer or by a specialist authorised by ATMOS if the device is used in another patient. Prior to passing on the device to another patient/user, the device must be reprocessed according to the manufacturer's guidelines.

How can one realise that the suction device is contaminated?
Perform a visual inspection of the condensate collector (at the device, see Fig. 1). In case of soiled or damped condensate collector, the device is oversucked and therefore contaminated.

In case you realise this incidents, it is necessary to have the device repaired by ATMOS or by a certified ATMOS partner.
If any reservations exist regarding the hygiene condition of the device, please send the device to ATMOS or a certi fied partner for inspection.

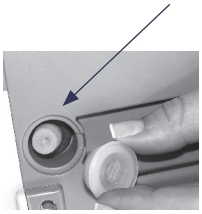


Fig. 1
condensate collector for a quick view control of a possible contamination

9.3 Battery handling

- Prior to first use, the battery must be fully charged!

- Total discharge may destroy the battery. Therefore, please fully recharge the batteries of the ATMOS C 161 Battery every 3 months, even if the device is not used.

- Battery-run devices should only be stored when they are fully charged.

- If the device was not in operation for a long period of time, the full capacity of the battery can only be achieved when 4 complete recharging and discharging cycles have been completed.

- Used batteries should be replaced immediately by the customer service. The mains operation of the device with used batteries can destroy the charging electronics respectively excessive power consumption of the device may result in a spontaneous cut-off.

- Heat destroys the batteries. Therefore, please prevent them from direct solar radiation and keep them away from radiators. The perfect storage temperature is between 8 – 15°C.

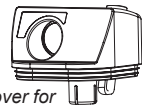
- The battery should be exchanged by the service department if the available capacity (operating time) is less than 80 % compared with a new battery.

10.0 Trouble-shooting

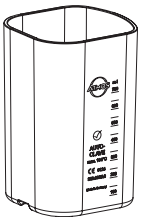
Prior to dispatch, the ATMOS C 161 Battery was subjected to an extensive functional test. If, nevertheless, a failure should appear, you may possibly clear it yourself if you follow these notes:

Problem	Possible causes	Remedy
● Unit does not start	– Discharged battery	– Connect the battery charging power pack to the device. The battery should be recharged for 1 – 2 hours prior to operation with battery.
	– Loose power plug of the charging device	– Check all plug and socket connections. Pay attention to the control lamp, it must be illuminated when all connections are o.k.
● Insufficient performance	– Discharged battery	– Recharge the battery.
	– Filter is blocked	– Exchange the filter.
● 1. Low or no vacuum is indicated	– 1.1 DDS bacterial filter is missing	– Insert DDS bacterial filter
	– 1.2 Leakages within the hose system or in collection jar lid	– Check collection jar lid and hose system on tight fitting. – Connect the filter once again to the connection nozzle. – Check the suction lid on tight and correct fitting.
	– 1.3 Secretion or blood has been sucked in and valve plates of the pump are contaminated	– Unit has to be returned for repair.
● 2. High vacuum is indicated	– 2.1 DDS bacterial filter is blocked.	– Exchange DDS bacterial filter
	– 2.2 Float of overflow safety closes the collection jar inlet	– Check collection jar inlet; if necessary empty secretion container, clean the oversuction protection and check float ball for flexibility.

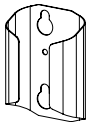
11.0 Accessories, consumables and spare parts



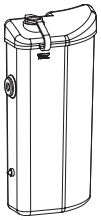
Cover for secretion container (incl. spare DDS filter)



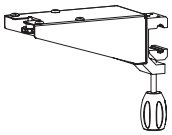
Grad. secretion container 1 l



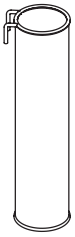
Rewind system for suction hoses



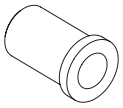
Separate rinsing container set



Device support

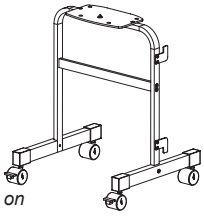


Basket for catheters

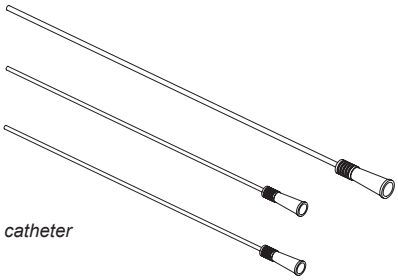


DDS bacterial filter / oversuction stop

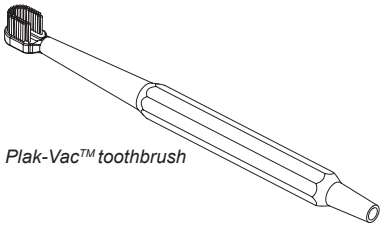
Hose connection, (fingertip)



Trolley on 4 castors



Suction catheter



Plak-Vac™ toothbrush

	REF
11.1 Accessories for ATMOS A 161 Battery	
Grad. secretion container 1 l, PPSU,	**313.0005.0**
Cover for secretion container (incl. spare DDS filter)	**313.0006.0**
Hose connector	**000.0836.0**
Rewind system for suction hoses	**313.0007.0**
Separate rinsing container set (incl. lid and support)	**313.0008.0**
Receptal® external container 1 l	**312.0464.0**
Holder for Receptal®-external container 1 l	**313.0009.0**
Medi-Vac® external container 1 l	**312.0473.0**
Holder for Medi-Vac® external container 1 l	**313.0010.0**
Charging device for ATMOS Battery	**313.0080.0**
Car connectiong cable (12 V) for ATMOS Battery (also for operation)	**313.0436.0**
Trolley on four castors, self mounting	**320.0070.2**
Carrying bag with practical storage pockets for consumables	**313.0011.0**
Device support with rotatable holder for attaching the unit to patient's bed, to a stand, wheelchair or standard rail etc.	**313.0012.0**
Basket for catheters, L = 340 mm	**444.0140.0**
Basket with standard rail holder	**320.0075.0**
11.2 Consumables for ATMOS A 161 Battery	
DDS bacterial filter/oversuction stop, hydrophobic, disposable, not autoclavable, 10 pcs., 50 pcs., 100 pcs., Change: 1 x per patient	**340.0054.0**
Suction hose, silicone, Ø 6 mm, L = 1.30 m, (134°C) Change: after 20 x autoclaving, every 4 weeks	**000.0013.0**
Suction hose, disposable, not autoclavable, Ø 6 mm, L = 1.30 m, with integrated funnel and finger tip, sterile, 10 pcs. Change: 1 x per patient	**006.0057.0**
Hose connector (finger tip), sterile, not autoclavable, price for 10 pcs. Change: 1 x per patient, with same patient every 2-3 days	**000.0347.1**
Hose connector (finger tip), sterile, not autoclavable, price for 100 pcs. Change: 1 x per patient, with same patient every 2-3 days	**000.0347.1**
Suction catheters, size: CH 12 (white Ø 4 mm) straight, central opening, 2 small lateral openings, L = 50 cm, suction connection Ø 6 mm, (disposable part, sterile, not autoclavable), 100 pcs. Change: after every application	**000.0294.0**
Suction catheters, size: CH 14 not autoclavable, (green Ø 4.7 mm) like CH 12	**000.0295.0**
Suction catheters, size: CH 16 not autoclavable, (orange Ø 5.3 mm) like CH 12	**000.0296.0**
Receptal® bag 1 l, 50 pcs., not autoclavable; Change: 1x per patient	**312.0463.0**
Medi-Vac® internal container 1 l, 50 pcs. not autoclavable, Change: 1 x per patient	**312.0474.0**
Plak-Vac™ toothbrush with suction mechanism not autoclavable, Change: 1 x per patient, with the same patient: every 4 weeks,	**000.0821.0**

11.3 Spare parts	REF
Hider	313.0022.0
Self-adhesive elastic buffer 5J-5017	000.0018.0
Bacterial filter/overflow protection	340.0054.0
Plug GPN 300	000.0824.0
Ball for overflow protection	000.0839.0
Power supply cord	008.0866.0

12.0 Technical specifications

Air flow rate of pump	20 ± 2 l/min
Max. vacuum	-76 kPa* (-760 mbar; -570 mmHg) ±3kPa
Vacuum readout	-1...0 bar (± 25 mbar) (mm Hg; kPa)*
Additional air regulation	mechanical regulating valve
Collection jar	1l DDS secretion container, 1l Receptal® container system or 1l MediVac container system
Suction hose	ø 6 mm, 1.30 m length
Voltage supply ((battery charging power supply))	100-240 Vac (+/-10%) 50/60 Hz
Low voltage supply	12 V DC ± 10%
Operation time during battery operation (without mains supply)	Battery operation approx. 40 min. Intermittent duty after 10 min (battery protection)
Operation time during mains supply 12 V DC (with 230 V battery charging power supply or 12 V battery charger leads)	Intermittent duty after 10 min (30 min. cooling down, depending on ambient temperature)
Emergency operation	In case of fully discharged battery, mains operation is possible
Power input (battery charging power supply)	max. 1.5 A
Power consumption	45 AV
Battery	7,4 V: 4,3 Ah; lithium-ionic
Charging time	approx. 1 h 30 min
Protective earth conductor resistance Earth leakage current Enclosure leakage current Patient leakage current	— — N.C. < 0,1 mA —
Heat emission	40 J/s
Noise level	56.0 dB (A) @ 1m (acc. to ISO 7779)
Ambient conditions Transport/storage	-30...+50°C 5...90 % humidity, non-condensing air pressure 700...1060 hPa
Operation	+10...+35°C 20...80 % humidity, non-condensing air pressure 700...1060 hPa
Dimensions HxBxT	250 x 255 x 180 mm
Weight	4 kg
Regular safety-relevant inspections	recommended: once a year
Protection class (EN 60601-1)	II
Degree of protection	Type BF
Protection category	IPX 0
Classification acc. to Annex IX, EC directive 93/42/EEC	IIa
CE marking	CE 0124
Rules applied	EN 60601-1: 1990 + A1: 1993 + A2: 1995 EN 60601-1-2: 2001 EN ISO 10079-1: 1999
UMDNS-Code	10-219 (tracheal suction device)

* 1 bar ≈ 750,06 mm Hg ≈ 1000 hPa / depends on daily atmospheric pressure Issue of Technical Specifications: 07.12.06

13.0 Checking / Reprocessing / Disposal

13.1 Checking ATMOS suction devices

The ATMOS suction devices are maintenance-free in the case they are used according to the operating instructions. However, regular safety-relevant checks have to be performed in line with the BGV A3/GUV 2.10 (MPBetreibV §2 Abs. (8)). “For mobile devices the safety-relevant controls must be performed at least every 12 months.”

Regular, thoroughly cleaning and disinfection of the hoses and the application parts respectively the operation in line with the operating instructions are assumed.

A regular check of the condensate controller on the rear side is necessary. Pull out the plastic plug and check the colour at the hose end. In case of discolouration/deposits a maintenance measure must be performed by a certified ATMOS service partner!

13.2 Reprocessing

In case of change in patient the device must be reprocessed prior to use with another patient in order to protect the user. The reprocessing may only be performed by the manufacturer or by an authorised specialist.

ATMOS MedizinTechnik GmbH & Co. KG offers their partners and customers a trouble-free and quick reprocessing and checking / safety-relevant control for ATMOS suction devices.

13.3 Disposal

- The ATMOS C 161 Battery is not comprised of any hazardous materials.
- The materials of the housing can be recycled completely.
- Prior to disposal, device and accessories must be decontaminated.
- The materials are to be separated carefully.
- Pay attention to country-specific regulations for disposal (e. g. waste incineration).

Disposal within the EC

The suction device described above is a high-quality medical product with a long service life. After its life cycle it must be disposed of professional. According to the EC directives (WEEE and RoHS) the device may not be disposed of in domestic waste. Please observe existing national laws and rules for disposal of old devices.

Disposal within the Federal Republic of Germany

In the Federal Republic of Germany the law for electrical devices (ElektroG) rules the disposal of electrical devices. Since this type of product is mainly used at home for secretion suction in the respiratory tract (after laryngectomy), it must be assumed that those suction devices could be contaminated. Therefore, this type of device is excluded from the law for electrical devices. In order to guarantee a proper disposal of your old device, please either pass on your old device to your specialised dealer or send it directly to ATMOS MedizinTechnik for a professional disposal.

Prior to disposal respectively before transport all secretion containers and hoses must be thoroughly cleaned, disinfected or sterilised. The device surface must be disinfected.

14.0 Notes on EMC

- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.

14.1 Guidelines and Manufacturer´s Declaration - Emissions

The ATMOS C 161 Battery is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 161 Battery should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The ATMOS C 161 Battery uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The ATMOS C 161 Battery is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Inapplicable	
Flicker IEC 61000-3-3	Inapplicable	

14.0 Notes on EMC

The device may not be used directly next to other devices or piled up with other devices.
If operation next to or piled with other devices is necessary, please watch the device to check its intended operation in this arrangement.

14.2 Guidelines and Manufacturer´s Declaration - Immunity for ATMOS C 161 Battery

The ATMOS C 161 Battery is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 161 Battery should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramis tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV symmetric ± 2 kV symmetric	± 1 kV symmetric	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips / Dropout IEC 61000-4-11	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30 % Dip of the U_T) for 25 Cycles < 5 % U_T (>95 % Dip of the U_T) for 5 s	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30 % Dip of the U_T) for 25 Cycles < 5 % U_T (>95 % Dip of the U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS C 161 Battery demands continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS C 161 Battery from an uninterruptible current supply or a battery.
Power Frequency 50/60 Hz Magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE U_T is the mains alternating current prior to application of the test levels.			

14.0 Notes on EMC

14.3 Guidelines and Manufacturer´s Declaration - Immunity

The ATMOS C 161 Battery is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C161 should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz bis 80 MHz	10 V	Portable and mobile communications equipment should be separated from the RS 221 incl. the cables by no less than the distances calculated/listed below. **Recommended distances:** d = 0,35 √ P d = 0,35 √ P 80 MHz bis 800 MHz d = 0,70 √ P 800 MHz bis 2,5 GHz where „P“ is the max. power in watts (W) and D is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (*a*) survey, should be less than the compliance level (*b*). Interference may occur in the vicinity of equipment containing following symbol 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz bis 2,5 GHz	10 V/m	

NOTE 1	With 80 MHz and 800 MHz the higher frequency range applies.
NOTE 2	These guidelines might not be applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.
a	The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS C 161 Battery is used exceeds the above compliance level, the ATMOS C 161 Battery is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the device.
b	Within the frequency range of 150 kHz to 80 MHz the field strength is to be below 3 V/m.

14.0 Notes on EMC

14.4 Recommended separations between portable and mobile RF Communications equipment and the ATMOS C 161 Battery

Recommended separations between portable and mobile RF Communications equipment and the ATMOS C 161 Battery			
The ATMOS C 161 Battery is intended for use in electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ATMOS C 161 Battery can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS C 161 Battery as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance, depending on transmit-frequency m		
Nominal output of the transmitter **W**	**150 kHz bis 80 MHz** **d = [0,35] √ P**	**80 MHz bis 800 MHz** **d = [0,35] √ P**	**800 MHz bis 2,5 GHz** **d = [0,70] √ P**
0,01	0,035	0,035	0,07
0,1	0,11	0,4	0,22
1	0,35	0,35	0,7
10	1,1	1,1	2,2
100	3,5	3,5	7,0
For transmitters for which the maximum nominal output is not indicated in the above table, the recommended separation distance *d* in meters (m) can be determined using the equation belonging to the respective column whereas *P* is the maximum nominal output of the transmitter in watts (W) acc. to manufacturer´s specification. NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies. NOTE 2 These guidelines might not be applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.			

Declaration of conformity

MedizinTechnik
... for a better life

EG - KONFORMITÄTSERKLÄRUNG
FÜR MEDIZINPRODUKTE

EC - DECLARATION OF CONFORMITY
FOR MEDICAL PRODUCTS

DECLARATION DE CONFORMITE C.E.
POUR PRODUITS MEDICAUX

Name / Adresse des Herstellers:
Name / Address of Manufacturer:
Nom / Adresse du Fabricant:

ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Straße 16
79853 Lenzkirch/Germany
Tel. +49 (0) 76 53 / 6 89-0

Wir erklären hiermit, dass das Produkt... / We hereby declare that the product... / Par la présente, nous déclarons que le produit...

Artikelbezeichnung / Designation / Désignation d'article:
ATMOS C 161 Battery / DDS..... Art.Nr. 313.0400.0

Varianten / Models / Variantes:
ATMOS C 161 Battery / R ..... Art.Nr. 313.0401.0
ATMOS C 161 Battery / M ..... Art.Nr. 313.0402.0

den grundlegenden Anforderungen der nachstehenden Richtlinie entspricht:
is in conformity with the following standards:
est conforme aux prescriptions données de la directive sous-mentionée:

- Richtlinie 93/42/EWG des Rates über Medizinprodukte vom 14. Juni 1993, zuletzt geändert am 7. August 2002
- Directions 93/42/EEC on medical products, passed by the commission on 14th June 1993, last amended on 7th August 2002
- Directive 93/42 du Conseil sur les produits médicaux du 14 Juin 1993, dernier changement le 7 Août 2002

Das Produkt wird gekennzeichnet mit:
The product is marked with the sign:
Le produit possède le marquage:

CE 0124

Lenzkirch, den 03.01.2007
Place and date of issue

ppa. Hans-Joachim Hoffmann
Sicherheitsbeauftragter / Safety Inspector

Zeitlich unbegrenzt gültig bis auf weitere Änderungen am Produkt.
Validity unlimited till further changes at the product.
Validitée non limitée à l'exception des changements au produit.

Qd 148-4_CE0124

ATMOS MedizinTechnik GmbH & Co. KG | Ludwig-Kegel-Str. 16 79853 Lenzkirch / Germany | Tel. : +49 7653 689-0 Fax: +49 7653 689-190 | atmos@atmosmed.de www.atmosmed.de

General Standard Terms and Conditions

1. General

Our General Standard Terms and Conditions apply exclusively. Client's terms and conditions which are contrary to or deviate from our General Standard Terms and Conditions are not recognised unless their validity is explicitly confirmed in writing. Our General Standard Terms and Conditions also apply even if we deliver to clients without reservation, in the knowledge of the client's contrary terms and conditions. Our General Standard Terms and Conditions also apply to all future business with that client.

2. Proposal - Order Confirmation

Our proposals are subject to change without notice unless otherwise stated in our order confirmation. Each order is only accepted by us following our written order confirmation.

3. Orders

Every order requires an exact description of all of our product's details. We assume no liability for errors and damage caused by inaccurate or incomplete ordering details.

4. Prices

Unless otherwise stated in the order confirmation, our prices in the order confirmation are ex factory prices and exclude packaging and value added tax. Packaging is charged separately at cost price in the invoice. Value added tax is charged separately in the invoice according to the legal rate on the invoice date. We reserve the right to change prices appropriately should price reductions or increases, especially due to wage settlements, changes in the price of materials or currency fluctuations, be incurred. Proof of such changes will be provided for the client on request.

5. Payment Conditions - Balancing

Unless otherwise stated in the order confirmation, our invoices are payable with a 2% discount within 14 days (except for repair and assembly services) or within 30 days from the invoice date net cash. We are entitled to charge interest after the due date at a rate 2% above the relevant basic interest rate of the German Federal Bank. Should the client have payment arrears, we are entitled to charge interest on arrears at a rate 5% above the relevant basic interest rate of the German Federal Bank. Should we be able to prove higher damages due to arrears, we are also entitled to claim these. The client only has the right to balance invoices against its own claims should such claims be confirmed in a court of law or recognised by us. The client does not have the right of retention due to disputed counterclaims.

6. Delivery Periods

Fulfilment of our delivery duties requires the punctual and proper fulfilment of the client's duties. The right to defense on the grounds of an unfulfilled contract is reserved.

Should the client default in accepting the goods delivery or breach other cooperation duties, we are entitled either to withdraw from the contract or claim compensation for any increased costs incurred up to that time without setting a further deadline. The right to make further claims is reserved. Furthermore, in such cases, the risk of coincidental destruction or a coincidental deterioration in the quality of the delivered goods is transferred to the client in the case of default in accepting such goods or payment arrears.

Acts of God or stoppages (due to insufficient supplies of material, industrial disputes etc.) entitle us either to demand an appropriate extension of delivery periods or to partly or entirely dissolve the delivery contract. This does not give the client the right to claim damages. We have fulfilled delivery periods if the delivery goods have left our factory or the client has been informed of the goods' readiness for delivery within such delivery periods. Delivery periods stipulated by the client are not recognised by us unless they form part of our order confirmation. We adhere to legal terms and conditions in cases where, as a result of an undue delay in the delivery for which we are liable, the client is entitled to claim that his interests in a continued fulfilment of the contract have ceased. We also adhere to legal terms and conditions should a delay in delivery be caused by deliberate or grossly negligent action by us or our representatives for which we are responsible. We are also responsible for such actions by our representatives or agents. Should the delivery delay not be caused by our deliberate infringement of contractual duties for which we are responsible, our liability is limited to damage which is regarded as typical for that case. We are liable according to the legal terms and conditions if and in so far as the delivery delay for which we are responsible is caused by an infringement of a substantial contractual duty. In such cases, our liability is also limited to damage which is regarded as typical for that case. Should the delivery delay be caused by a culpable infringement of non-substantial contractual duties, our client is also entitled to claim a one-off damage compensation worth 3 percentage points of the delivery value of the goods for each week's delay, up to a maximum which is no higher than 15 percentage points of the delivery value of the goods.

7. Delivery - Familiarisation

In the case of the delivery of devices for the medico-technical industry which require assembly and/or familiarisation for the final customer using specialist trade personnel (such as Ear, Nose and Throat Apparatus and Suction Units), we reserve the right to deliver the goods exclusively to the relevant specialist traders. Should the trader not carry out assembly and/or familiarisation for the final customer, this is carried out by us. In such cases, we reserve the right to charge the client for the additionally created costs. Our specialist traders operate a recording system so that, if necessary, our products can be traced to the final customer. The specialist trader undertakes to immediately report to us all events and risks which must be reported in connection with our products.

8. Passage of Risk - Packaging

Unless otherwise stated in our order confirmation, delivery is agreed ex factory. The risk of the goods' damage or loss is therefore transferred to the client as soon as the goods leave the factory or the client is in default of acceptance of the goods. This also applies to cases where we confirm prepaid carriage. Transport packaging and all other packaging according to the packaging regulations is not returnable. Our client is responsible for disposing the packaging at its own cost. Our deliveries are insured by us at the client's expense unless explicitly otherwise agreed. No insurance is arranged in the case of goods which are collected by our clients. In the case of transport damage, claims are only handled if the client receives confirmation of any damage, reduced weight or loss by the shipping company before accepting the delivery.

9. Warranty

The client is responsible for examining the delivered goods immediately after receiving them to determine any eventual deficiencies or delivery errors, and to report these immediately. Should the client fulfil this examining and reporting responsibility, and should payment conditions be fulfilled, we shall be liable to the client within the scope of legal regulations.

Our period of warranty shall in all cases be two years.

Our client can make use of the warranty as follows, so long as he can provide first buyer proof (in the form of an invoice or delivery note) and provided that the product still has the original, unchanged serial number:

a. We choose whether to fulfil our guarantee by providing repair services free of charge - either on the client's premises or in our factory - or replacing the product. We can also provide these guarantee services through an authorised company;

b. Should a product be returned to us, the client agrees to send the product in its original or similar packaging, offering the same protection as the original packaging, to our address or any address notified by us.

c. Our guarantee ceases to apply if changes of any kind have been made to our product, unless such changes have been made by us or a company authorised by us, or have been previously agreed upon in writing by us. Our guarantee also ceases to apply if third parties have carried out repairs to our products or replaced parts thereof. This applies regardless of the fact whether these measures individually or collectively led to a deficiency of the product;

d. We accept no responsibility for damage defects caused by
- operational wear and tear;
- incorrect installation or incorrect or insufficient maintenance;
- incorrect operation of the product (in contradiction to the handbook delivered with the product);
- improper use or operating faults;
- inappropriate or negligent handling and care, especially with respect to dirt, lime, suction of fluids, inappropriate cleaning and sterilisation;
- using accessories and/or replacement parts which are not explicitly approved;
- incorrect assembly and/or initial operation by the client or third parties;
- the client's negligence in handling the product;
- unacceptable operating conditions, such as humidity, temperatures, the power supply, vibrations.
- accidents, acts of God, especially lightening, water, fire, public unrest and insufficient ventilation.

We are not liable for damage to other objects apart from our product itself, except in the case of any deliberate or grossly negligent actions by us or our representatives or agents. Should no deliberate breach of contract be claimed, our liability is limited to damage which is regarded as typical for that case. This also applies in the case of our culpable infringement of substantial contractual duties. The indispensable conditions of German Liability Law remain unaffected thereby.

- For second-hand equipment, the period of warranty shall be reduced to a period of twelve months.

10. Reservation of Ownership

We retain ownership of our goods until the receipt of all payments arising from the business relationship, including all demands arising from installation orders, subsequent orders, repairs, accessory deliveries and replacement orders. Should we have agreed upon payment on the basis of cheque and bill transactions, the ownership reservation applies until the cheque received by us has been paid in, and does not expire through our credit upon receiving the client's cheque. In the case of a breach of contract by the client, especially payment arrears, we are entitled to repossess our goods. Repossession of our goods represents a withdrawal from the contract, unless explicitly declared in writing by us. We have the right to utilise the product after its repossession, whilst the income form such use is balanced against the client's arrears, after deducting appropriate utilisation costs.

The client is responsible for handling the goods with care. Should maintenance and inspection work be necessary, the client must carry these out punctually at his own cost. Our client is entitled to sell the goods he has bought from us in a proper sale transaction. However, he must immediately assign all outstanding claims to the value of the final invoice sum (including value added tax) of our claims to his customers or third parties. The client is entitled to collect this claim even after such assignment. Our right to collect the claim ourselves remains unaffected thereby.

We undertake to release the securities to which we are entitled if requested to do so by the client should the realisable value of the our securities be more than 10 percentage points higher than the outstanding claims. We reserve the right to choose the securities to be released.

11. Plans and Illustrations

We retain ownership of and copyrights to all plans, illustrations, calculations and other documents which are attached to our proposals. The client must receive explicit written permission before passing these on to third parties. Imitating our legally patented products is forbidden and will be prosecuted.

12. Jurisdiction and Place of Performance

Our central office is the place of performance for all disputes in connection with these General Standard Terms and Conditions and the contracts closed with clients under them. This jurisdiction excludes other jurisdiction relating to persons or subject-matter. Furthermore, our client is not entitled to bring charges against us in another court should he file counter-charges, carry out counterbalancing or declare retention. We, however, are entitled to bring charges against our client at their general place of jurisdiction or at another relevant court recognised by German or foreign law.

Unless otherwise stated in the order confirmation, our central office is the place of performance.

Lenzkirch, December 01, 2001

ATMOS MedizinTechnik GmbH & Co. KG
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