LIFETIME SA01/02/03/04PB
Surgical Aspirators

User Manual





CE 1984

Please read this manual thoroughly before use the device.

Table of contents

1. Overview	3
1.1 Special signs on device	4
2. Product descriptions	5
2.1 Intended usage	5
2.2 Descriptions of functions	5
3. Safety information and notices	6
4. Installation	7
4.1 Installation with wall mounting plate	7
4.2 Installing the accessory bag	7
5. Usage	8
5.1 First operation	8
5.2 Aspiration	8
5.3 Ending aspiration	9
5.4 Charging the aspirator	9
6. Hygienic preparation	10
6.1 Preparation	10
6.2 Cleansing, disinfection and sterilization	10
6.3 Reassembling components	11
7. Function control	11
7.1 Maintenance Intervals	11
7.2 Performing a function check	11
8. Faults and troubleshooting	12
8.1 Battery	13
8.1.1 Replacing battery	13
8.1.2 Calibrating the battery indicator	13
9. Maintenance	13
9.1 Periods	13
9.2 Disposal	14
10. Delivery contents	14
10.1 Standard delivery	14
11. Technical specifications	14
12. Warranty	15
13. Certificates	15
14. Electromagnetic compatibility (EMC) declaration	16

Glossary of symbols

Caution Consult Accompanying Documents

Class Ii Equipment

Conformite Europe

Date Of Manufacture

IPX1 Protection Against Vertically Falling Drops

Should Be Disposed According To Weee Directives

Manufacturer

Type B

SN Serial Number

Type Bf

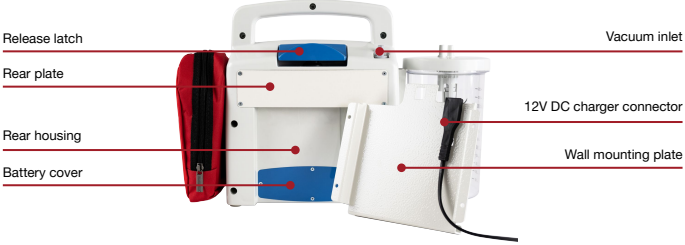
1. Overview

All four models — SA01PB, SA02PB, SA03PB, and SA04PB — share the same external design and component layout. The differences lie in suction capacity (20 LPM or 30 LPM), and in the type of user interface: SA01PB and SA02PB use manual vacuum control, while SA03PB and SA04PB feature digital vacuum control.

1.1 Front view of the surgical aspirator device with reusable collecting jar



1.2 Rear view of the surgical aspirator device



1.3 Control panel view



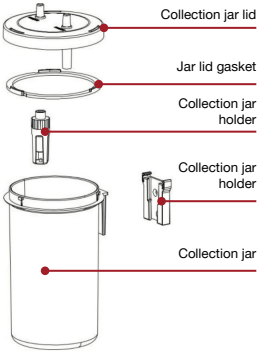
Manual vacuum control interface
(SA01PB, SA02PB models)



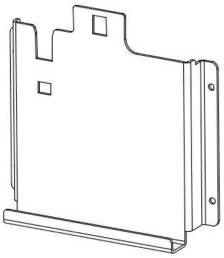
Digital vacuum control interface
(SA03PB, SA04PB models)

1.4 Accessories

Reusable collection jar



Rear mounting plate



Hydrophobic filter



1.5 Special signs on device

Connection markings

The reusable collection jar is marked to indicate correct hose connections:

- The port labeled “VACUUM” must be connected to the device (suction side).
- The port labeled “PATIENT” must be connected to the hose leading to the patient.

> ⚠ **Important !**
> Incorrect hose connections may disable the overflow protection system, allowing fluid to enter the suction pump and cause damage.
> To minimize infection risk, the hydrophobic filter located between the device and the collection jar must be either replaced after each use or sterilized according to the IFU.

Battery indicator and warning LED

The battery indicator shows the current charge level. A warning symbol appears when the battery approaches over-discharge levels.

The device must be recharged before the red warning LED activates — or immediately after if already lit.

If the battery is not charged and the device continues operating, it will shut down automatically when critically low. A 6-second audible and visual alert will signal the shutdown.

2. Product descriptions

2.1 Intended use

Surgical aspirator is designed for temporary use in children and babies, it is a mobile, portable, electrical and medical suction pump. Its intended uses include:

Aspiration of blood, secretions and food particles from mouth cavity, as well as nasopharynx and bronchial system, Discharging the air from vacuum stretcher and vacuum splints. Provided that surgical aspirator is used in line with the rules suggested by the manufacturer, it may rule out the obstructions in respiratory tracts thereby eradicating the possibility of respiration cease. This device can be used inside buildings, in an open area and during transportation.

Surgical aspirator vacuum aspirator will not be used in the following areas:

In medical condition requiring a potential balancing (for instance: cardiac surgery)
In places where explosion danger is available
For drainages in low vacuum intervals (for instance: wound drainages or thoracic drainages)

Usage areas of the device

It is used to aspirate blood, secretions and food particles from the oral cavity, nasopharynx and bronchial system.

Side effects

The device should only used by people who has medical training and adequate knowledge of suction technique. Improper use and practices can cause serious bodily harms.

In case of there is a mistake with the suction process, patients may have injuries in their mouth,pharynx especially in their mucosa.

Not using sterile suction catheters can cause infection and bacteriological contamination risks for the patients.

Patient population

All patients aged 2 years and over 10 kg in need of surgical aspiration.

Target user

Qualified medical professionals and their instructors.

Indications

It uses accumulations such as blood, secretions and food particles to be aspirated from any body part such as the mouth, nose-pharynx, bronchial system. It is used for aspiration of blood body fluids in surgical operations. It is also used to clean the airway from blood, saliva, vomit or other secretions so that the patient can breathe. Used following tracheotomy and for patients with tracheostomy. Aspiration can prevent pulmonary aspiration that can lead to lung infections. Aspirator is also used in operations such as removal of blood accumulated after intracranial hemorrhages, delivery and abortion in the operating room and clinic that require aspiration.

Contraindications

The usage level of aspirators is important. Excessive aspiration or prolonged aspiration to the same point causes tissue damage and unwanted bleeding. Not using the tips for the patient or not being sterile creates the risk of contamination and infection. It should not be used when opening the airway in patients with severe bronchospasm or laryngeal spasm, with a gag reflex. Its use on fistulas may increase bleeding. It is not suitable for patients under 2 years of age and weighing less than 10 kg.

2.2 Descriptions of functions

An electrical pump with piston gives the vacuum pressure required for aspiration. The device can be optionally functioned with mounted rechargeable batteries or connected to an external direct current source of 12.0 - 13.8 V. With a vacuum setting unit, it is possible to select a vacuum power between –100 mmHg and -650 mmHg. Keypad is lighted to be used in dark environment.

Upon accessing the vacuum pressure you select, the device initiates to function in a fixed circle. In the event that the vacuum pressure is modified, the pump rearranges the circle in order for arranging the selected vacuum pressure.

Surgical aspirator gradually decreases the performance when it reaches to vacuum power required. All the contents aspired reach the collection jar via aspiration hose.

Reusable collection jar

The reusable collection jar is mounted on the side of the main unit. A hydrophobic filter, positioned between the device and the jar, prevents the entry of bacteria and fluid droplets into the main unit. It also helps reduce dispersion thanks to the integrated vibration-damping set.

If the hydrophobic filter becomes wet, shows signs of contamination, or discoloration is observed, it must be replaced immediately. Additionally, the filter must be replaced after use on any patient with a suspected risk of contamination.

Never wash, sterilize or autoclave the hydrophobic filter.

Important !
Excessive filling prevention assembly prevents the secretion from going into main unit. Closing plug in the surface of the secretion obstructs the exit when the secretion reaches to a certain level.

Power Supply

The device can be powered in the following ways:

- Using the internal battery
- Using the car charger connected to a 12 V vehicle outlet
- Using the mains power charger connected to a standard AC socket

The battery indicator shows the current charge level. When the device is connected to an external power source, charging starts automatically.

3. Safety information and notices

For your own safety as well as for your patient's safety, please take the following points into consideration in line with the requirements of MDD 93/42/EEC:

- Please use surgical aspirator device solely for the intended uses.
- Please read these instructions for use carefully. This manual is integral part of the device and it should ready every time.
- Prior to operating surgical aspirator device, you should be aware of the relevant information about the use of device.
- Only if you have adequate information and medical education about suction technique can you use surgical aspirator device. Inappropriate use and applications may cause serious body damages.
- Please take care that no injuries occur in mouth and pharynx particularly in the mucosa during the suction procedure.
- During bronchial suction procedure, operate the device by obeying the sterility rules and use only sterile suction catheter.
- In the event that the device is operated with reusable container, the device should always be standing as the otherwise condition causes the unsafe closure of the connection to the pump thereby leading to the secretion going into suction pump. That condition may cause damage in the pump.
- When the disposable container is used, the device should be standing. Therefore, you can prevent the scattering of fluids or secretions into over filling filter which is integrated into disposable container. If you cannot avoid this, the feature of air permeability of the overflowing filter disappears and you will need to replace the suction bag which is used only once.
- Due to the possibility of being out of order of the device, we recommend you to have an alternative suction system.
- Please take the Part 6 "Hygienic Preparation Procedures" into consideration in order to rule out any infections or bacterial contamination.
- In the event that foreign materials are used, partial malfunctions might appear. Additionally, biological compliance associated requirements might not be met. In such cases, if the accessories recommended in the instructions for use are not used, nor are the original spare parts used, please be known that all the warranty and responsibility provisions shall become null and void.
- Please let the all audits and repairs be performed by manufacturer, ELMASLAR or its specialized staffs.
- In order for extending the life of batteries, they should never be discharged extremely. Please charge the batteries when the capacity indicator red light 10% is active at the latest.
- In order to avoid the extreme discharge, please never store surgical aspirator device as uncharged. Firstly charge the batteries as required.
- The batteries are discharged when they are not used. Their self discharging ratio enhances with the heat and if they are used at the 20°C for 1.5 months, this ratio is approximately 50%. Therefore please consider the function control intervals.
- Do not immerse hydrophobic filter into disinfection fluid, otherwise the features of the filter disappear.
- The device should not be sterilized in autoclave.
- Do not submerge the the device into a disinfection solution.
- Do not use wireless phone (mobile phone) nearby surgical aspirator. Even if a mobile is used in the driver's cabinet, using Surgical aspirator device in the patient's cabinet of the ambulance does not cause any problems.

4. Installation

4.1 Installation with wall mounting plate

Important !
The surgical aspirator is delivered ready for use. Before first use, make sure to fully charge the device.

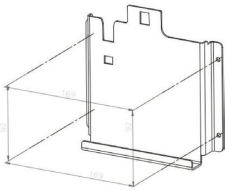
If the wall mounting plate is not included in your package, it can be ordered as an accessory.

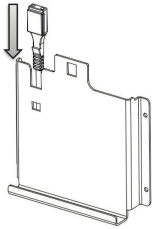
Use the supplied metal nuts only when mounting the stabilizer onto the designated base plate (e.g., in vehicles). If you plan to mount the stabilizer to a different surface or structure, you must use appropriate hardware suitable for that material. These additional mounting components are not included in the delivery.

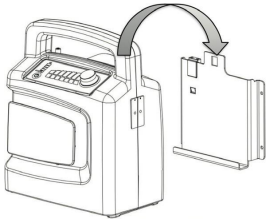
1. Choose a flat, vertical mounting surface.
2. Use the supplied installation template to mark the mounting area; the corner lines indicate the required installation space.
3. Hold the template against the wall and align it using a spirit level.
4. Mark the drilling points.
5. Drill holes using a 3 mm drill bit.
6. Mount the wall mounting plate using the screws provided.
7. Insert the connector of the charging cable into the guide channel and push it upward until it locks into place.

Note: The mounting surface must support the weight of the device and meet the installation safety requirements of EN 1789 for ambulance use.

8. Connect the car charger to a 12V DC outlet or plug the AC charger into an AC power socket (the charger supports 100-240V AC, 50Hz/60Hz).
9. Place the surgical aspirator into the wall mounting plate. Charging begins automatically, whether the device is on or off.
10. To remove the device, press the unlock button and lift the aspirator upward.







4.2 Installing the accessory bag

If the accessory bag is not included in the delivery, it can be ordered separately. The bag is designed to securely store aspiration catheters and other small components.

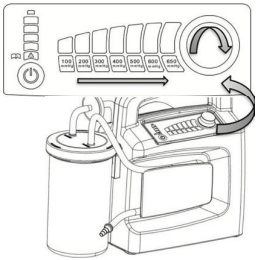
1. Attach the bag to the side of the aspirator housing using the touch-and-close fasteners.

5. Usage

5.1 First operation

Recommendation: Upon using the reusable container, prior to initiating the aspiration procedure, filling approximately 50-100 ml disinfection fluid or water will facilitate the cleansing procedure. The parts vacuumed will not be adhered into the bottom of the collection jar thanks to this method.

1. Remove the aspiration hose from the hose wrapping plate.
2. When required adapt an appropriate sized aspiration catheter for tracheal or nasopharyngeal aspiration.



Important !
To effectively aspirate viscous or dense materials such as food particles, remove the end piece from the aspiration hose and use the hose alone.

3. Press the O/I button. After the device is turned on, it initiates to start in the lowest vacuum level.
4. Select the vacuum power by turning the switch button.
5. Surgical aspirator is ready for operation now and you can initiate the aspiration procedure.

5.2 Aspiration

- During the aspiration procedure, take care that no injury occurs in the mouth and esophagus particularly in the mucosa.
- When the device is fully charged it can operate in the highest level of vacuuming for minutes continuously. By shutting the device down after a 45 minute of continual operation, you can avoid the overheating of the device. Please wait for at least 2 hours for cooling the device.

Important !
When using a reusable collection jar, the device must remain in a vertical position. If tilted, the overflow protection ball (buoy) may not close properly, allowing fluids to enter the suction pump and potentially cause damage.

- If operated with a single-use container, in order for avoiding the obstruction of the overflow valve integrated into container by the saliva, the device should always be standing vertically. If the fluid is scattered onto the overflow valve, it becomes air resistant and the single-use container should be changed.

Information:
During aspiration, monitor the collection jar visually. Empty the collection jar once it reaches approximately 950 ml to prevent overflow and avoid contamination that would require additional cleaning.

If the system activates before the collection jar reaches the full level, pause the aspiration process briefly to allow the system to ventilate.

Important !
Monitor the battery status during aspiration. If the red LED on the battery indicator lights up, switch to a backup device immediately. Continuing operation in this condition can lead to deep discharge, potentially damaging the battery and significantly reducing its capacity.

Discharging air from the system

1. Disconnect the hose between the device and the collection jar near the jar connection.
2. Wait until the overflow protection ball (buoy) drops back into position.
3. Reconnect the hose between the device and the container.
4. You may now resume the aspiration procedure.

Emptying the reusable collection jar

When the reusable collection jar reaches the full level, stop the aspiration process and empty the jar.

To prevent accidental detachment of the jar lid and make removal easier:

1. Disconnect the aspiration hose from the hose wrap plate.
2. Detach the collection jar from the aspirator.
3. Carefully remove the jar lid.
4. Empty the contents of the jar.

Important !
Do not remove the jar lid from the jar prematurely, and avoid accidental spillage during handling.

After emptying:

5. Reattach the saliva cover to the jar.
6. Hang the jar back onto the main unit, ensuring the cover is correctly aligned and locked in place.
7. If disconnected, reinsert the aspiration hose.

Important !
Follow local regulations and instructions for proper disposal of aspirated materials.

You may now resume the aspiration procedure.

5.3 Ending aspiration

After completing the aspiration procedure:

1. Press the O/I button to turn off the aspirator.
   When the device is turned off while in operating mode, the front panel indicator lights will remain active for approximately 10 minutes, allowing the device to be located in a dark environment.
2. Empty the collection jar (see section “Emptying the Reusable Collection Jar”).
3. Clean the aspirator (see section “6. Hygienic Preparation”).

5.4 Charging the aspirator

To ensure optimal availability, we recommend charging the device before the battery reaches its lowest level. This provides sufficient operating time for the next use.

The aspirator features a smart charging control system that manages optimal charging performance. It supports both fast and slow charging modes, automatically preventing overcharging and protecting the battery from damage.

The device requires a 12.0–13.8 V DC power source (max. 8 A). Full charge: approximately 2 hours.

Supported charging sources:

- 12V DC supply from a vehicle electrical system (available as an accessory)
- AC adapter/charger (available as an optional accessory)

Warning:
Ensure correct polarity when connecting to a vehicle power socket. Incorrect connections may damage the device.

Charging without the wall mounting plate

1. Insert the charging connector into the port on the back of the device and press it gently until fully seated.
   Make sure the “+” and “–” terminals align with the polarity markings on the device.
2. Turn on the power supply.
3. Within a few seconds, the charging process will begin automatically.
   Progress is shown via the battery indicator lights. When charging is complete, all lights remain steadily lit.

Charging with the wall mounting plate

- Mount the device onto the wall mounting plate.
- Turn on the external power supply.
- The device will begin charging automatically within a few seconds.
  The battery indicator lights show progress. When charging is complete, all lights remain steadily lit.

6. Hygienic preparation

Some parts of this product are single-use. These components are intended for one-time use only and must not be reused. Reusing single-use parts may compromise device performance and safety, and could lead to wear, degradation, or unexpected reactions due to thermal or chemical exposure.

The aspirator and its accessories must be hygienically prepared daily and before use with a different patient. Always follow the disinfection agent manufacturer's instructions.

After hygienic preparation, perform a full function check of all components (see section *7.2 Function controlling*).

Important !
Do not immerse the main unit in any disinfectant or liquid. Clean the main unit only with a damp cloth as described in section *6.2 Cleansing, disinfection, and sterilization*. Liquid exposure may cause device damage and pose a risk to operators and patients.

6.1 Preparation

To remove the reusable container:

1. Disconnect the aspiration hose from the hose wrap plate to reduce strain on the lid.
2. Pull the lock tabs outward and lift the container upward to detach it from the main unit.
3. Remove the jar lid carefully.
4. Empty the container.
5. Remove the ball (buoy) from the overflow protection assembly by rotating it counterclockwise.
6. Remove the sealing ring from the jar lid.

Important !
To avoid accidental spillage or removal of the jar lid while emptying the reusable container, handle the container carefully.

Important !
Follow proper disposal procedures (see section *3. Safety Information and Notices*).

6.2 Cleansing, disinfection and sterilization

Perform the hygienic preparation of the aspirator and its accessories according to the procedures listed in the table below. Always follow the instructions for use provided by the manufacturer of the disinfection agent.

For the disinfection process, it is recommended to wear household or disposable protective gloves.

Part	Component	Cleaning	Disinfection	Machine Wash	Sterilization
Reusable collection jar	Overflow float (from overflow valve)	Clean with warm water and mild detergent	Immerse in diluted disinfectant (1)	up to 95 °C	Not applicable
	Bacteria filter	Single-use; must be replaced after each patient			
	Jar (container body)	Clean with warm water and mild detergent or soft cloth	Immerse in diluted disinfectant (1)	up to 95 °C	Steam sterilize up to 121 °C (2)
	Jar Lid	Clean with warm water and mild detergent	Immerse in diluted disinfectant (1)	up to 95 °C	Not applicable
Single-use container		Single-use; must be replaced after each patient			
Main unit		Wipe with a soft, damp cloth	Wipe with disinfectant-moistened cloth	Not allowed	Not applicable
Accessory bag		Clean with mild detergent	Immerse in diluted disinfectant (1)		Disinfection-safe up to 40 °C

(1) After disinfection, rinse all parts thoroughly with distilled water.
(2) For components suitable for steam sterilization, follow EN 285 guidelines: autoclave at 121 °C with a holding time of 20 minutes.

6.3 Reassembling components

After completing the cleaning, disinfection, or sterilization procedures, reassemble the components as follows:

1. Insert the overflow float into the jar lid by turning it clockwise.
2. Fit the seal securely into the groove on the jar lid.
3. Place the jar lid onto the collection jar.
4. Attach the aspiration hose to the lid connection.
5. Mount the collection jar securely onto the main unit.

7. Function control

Before reusing the device, any detected malfunction or deviation from expected values during function testing must be resolved. The aspirator must not be used again until the issue is corrected.

Recommended spare parts:

- Single-use front component
- Hydrophobic filter

7.1 Maintenance intervals

When	Action
Before each use	Perform a functional check (see section 7.2 Function Control).
After each use	Clean, disinfect, or sterilize the device and its components (see section 6. Hygienic Preparation). Perform a functional check (see section 7.2 Function Control).
Every 6 weeks	Check the battery status. Turn on the device and inspect the battery indicator. If the level is at or below half, recharge the battery (see section 5.4 Charging the Aspirator).
At least every 6 months	Perform a full functional check (see section 7.2 Function Control).
After any repair	Clean, disinfect, or sterilize the device and its components (see section 6. Hygienic Preparation). Perform a functional check (see section 7.2 Function Control).

7.2 Performing a function check

Before use, perform the following checks to ensure the device is operating correctly:

1. Inspect all hoses, the collection jar, jar lid, and hydrophobic filter for any signs of damage, wear, or contamination. Replace any defective or torn components.
2. Verify that all hose connections are secure, the jar lid is properly seated, and the collection container is correctly mounted onto the main unit.
3. Switch on the aspirator. The device will start at the lowest vacuum level and display the current battery status via the battery indicator. Visually check the charge level. If necessary, charge the battery *(see section 5.4 Charging the Aspirator)*.
4. Close the suction inlet of the aspiration hose using your thumb.
5. Operate the device and set the vacuum level to –650 mmHg (maximum). The aspirator should reach this pressure within approx. 10 seconds.
6. Confirm that the device has reached the target vacuum level by observing the following:
   - The LED indicators from –100 mmHg to –600 mmHg light up sequentially.
   - The –650 mmHg LED begins flashing.

   If the device fails to reach this vacuum level within 10 seconds, suction power is insufficient. Check for potential issues *(see section 8. Faults and troubleshooting)*.
7. Open the suction inlet by releasing your thumb.
8. Switch off the aspirator.

8. Faults and troubleshooting

Description of Fault	Underlying Reason	Solution
Device not operating, O/I indicator and capacity indicator band shows the device is ready for operation.	Pump fault	Enable the device to be repaired by the manufacturer or authorized specialist.
Device not operating, O/I indicator shows the device is ready for operation.	Fuse fault	
	Fuse fault in the vehicle socket	
	Battery group over discharged.	Repeat the charging and discharging procedures for several times. If the result is the same, change the battery group.
	Polar connections in the vehicle socket are reverse.	Correct the incorrect polar connections and change the fuses if required.
	Connection between circle plate and battery group is not well inserted.	Do the interconnection entirely.
Device is not opened or closed.	Electronic circle fault	Make the device repaired.
The device cannot reach the maximum vacuum pressure of -650 mmHg for 10 seconds, but the capacity indicator band shows the device is ready for operation.	There are leakages in the suctioning parts of the device.	Check whether the hose connections, filter cover and saliva cover be inserted appropriately or not.
	Battery group is not sufficiently charged.	Charge the battery group.
	Pump fault.	Make the device repaired by the manufacturing plant or authorized specialist.
At the -400 mmHg suction level or higher suction level LED light for -200 mmHg or -300 mmHg is continuously active.	Bacteria filter is full.	Insert a new filter.
Charging procedure is not performed.	External power feeding is so low.	External power feeding should be between 12.0 and 13.8V DC.
Charging procedure is not performed. 100% LED light is not active when the charging procedure is completed.	Battery group overheated. Charging is impossible in the temperatures more than +45°C.	Make the temperature of the device lower under +45°C.
	Battery group overcooled. Charging is impossible in the temperatures less than +5°C.	Make the temperature of the device higher over +5°C.
	Fuses fault.	Make the device repaired by the manufacturing plant or authorized specialist.
	Fuse in the vehicle socket fault.	Change the fuse.
	Connection between circle plate and battery group is not correct and entire.	Do the connection thoroughly.
	The charger does not have the required features.	Use the original adapter/charger and/or accessories.
When the charging procedure is over 100% LED light is not active.	The current supplied by the vehicle electric installation is not between 12.0-13.8 VDC	Check the vehicle electric installation.
	Capacity counter setting is abnormal.	Discharge the device until it automatically stops and charge it until it is fully filled without operating it, afterwards.
	Due to over discharging, the battery group damaged.	Repeat the charging and discharging procedures for several times. If the result is the same, change the battery group.
	The battery group ended its life.	Repeat the charging and discharging procedures for several times. If the result is the same, change the battery group.

8.1 Battery

8.1.1 Replacing battery

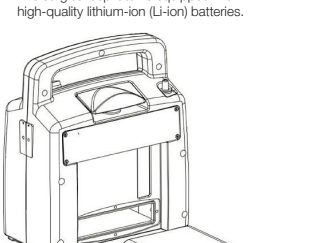
> **Important:** To avoid damaging electronic components, do not touch the control PCB during this procedure.

1. Power off the surgical aspirator.
2. Disconnect the device from any external power source.
3. Remove the collection jar and any attached accessories, if present.
4. On the back of the device, unscrew the four cross-head screws securing the battery compartment cover.
5. Carefully disconnect the battery connector from the main board.
6. Remove the faulty battery.

> **Note:** Before installing the new battery, wait approximately 30 seconds to allow internal capacitors to discharge.

7. Place the new battery into the compartment.
8. Carefully reconnect the battery plug to the main board.
9. Reattach the battery cover and secure it with the screws.
10. Perform a functional check *(see section 7.2 "Function Check")*.
11. Calibrate the device (see below).

Battery
The surgical aspirator is equipped with high-quality lithium-ion (Li-ion) batteries.



> **Note:** If the control board and battery are not calibrated together, the red LED on the battery indicator may blink intermittently even if the device is fully charged. The device remains operational, but the charge level may not display correctly.

8.1.2 Calibrating the battery indicator

Calibration ensures that the charge level displayed matches the actual charge of the battery.

Calibration is required:
- After each battery replacement
- After replacing any internal fuses

Calibration procedure:

1. Discharge the aspirator by running it until it shuts off automatically.
2. Connect the device to external power to begin charging. A full charge takes approximately 2.5 hours.
3. If the battery overheats during use, charging will begin automatically once the battery temperature drops below 40 °C.
4. In cases of high residual capacity, cooling before charging may take up to 45 minutes.

9. Maintenance

9.1 Periods

Surgical aspirator device does not need any maintenance. Nevertheless, please consider the periods for the regular functions ("See the section 7.1 Periods"). In order for protecting the life of the batteries and battery groups we recommend you to calibrate the battery group as per the section 8.1.2 once in every 8 weeks. Thanks to this method, the battery group is discharged under control and recharged afterwards. We recommend you to perform the audit and repair procedures by the manufacturer ELMASLAR or other authorized and specialized staff.

9.2 Disposal

Do not dispose this device together with the domestic wastes. Please refer to electronic waste collection authority authorized and certified in order to dispose the device according to the relevant rules. You can learn the addresses from the environment protection authorities or municipality. The package of the device (including the box and supporting parts) can be disposed as waste paper.

Disposing the batteries /battery sets

Do not dispose the used batteries/battery sets together with the domestic wastes. Please refer to ELMASLAR or public and/or legal disposal authorities.

10. Delivery contents

10.1 Standard delivery

- Surgical aspirator (main unit)
- Reusable collection jar
- Connection cable
- Hydrophobic filter
- Wall mounting plate set
- Accessory bag

11. Technical specifications

Parameter	SA01PB / SA03PB	SA02PB / SA04PB
Suction capacity (±10%)	20 L/min	30 L/min
Motor power	30 W	55 W
Operating time after 2 hours of charging (±10%)	90 min	60 min
Container volume	1000 ml	
Maximum vacuum (at sea level)	–650 mmHg	
Rated voltage	12 VDC	
AC charger (optional accessory)	100-240V AC, 50Hz/60Hz	
Battery type	Lithium-ion, 4.5 Ah	
Charging voltage range	12.0 – 13.8 V	
Charging time	Approx. 2.5 hours	
Maximum operating current	8 A (operation + charging)	
Device socket fuse	8 A	
Internal fuse – input line	4 A glass fuse, 5×20 mm, IEC 127 compliant	
Internal fuse – battery line	4 A glass fuse, 5×20 mm, IEC 127 compliant	
Sound level	≤ 60 dBA	
Dimensions (W × H × D)	375×290×140 mm (with reusable container)	
Weight	Approx. 4.5 kg	
Operating temperature & humidity	0 °C to +40 °C, 30% to 75% RH	
Charging temperature & humidity	0 °C to +40 °C, 30% to 75% RH	
Storage temperature & humidity	–40 °C to +70 °C, 30% to 75% RH	
IEC 60601-1 Classification	Class II, Type BF, IPX1	

12. Warranty

From the date of purchase, ELMASLAR warrants this product to be free from material and manufacturing defects for two (2) years, provided it is used as intended and in accordance with the Instructions for Use (IFU).

For products with a shorter shelf life (as indicated on the packaging or in the IFU), the warranty is valid until the stated expiration date.

A valid purchase receipt or invoice with dealer name and purchase date is required for any warranty claim.

Exclusions

The warranty does not cover:

- Use not in accordance with the IFU
- Misuse or improper handling
- Unauthorized repairs or modifications
- Use of non-original spare parts
- Damage during return shipping due to inadequate packaging
- Force majeure (e.g. lightning, flooding)
- Lack of required maintenance
- Normal wear and tear during use

ELMASLAR assumes no liability for damage resulting from intentional misuse, gross negligence, or injuries caused by slight negligence.

ELMASLAR reserves the right to repair the product, provide a replacement, or offer a partial refund at its discretion.

If a warranty claim is rejected, ELMASLAR is not responsible for shipping or handling costs.

This warranty does not limit any rights granted under applicable national laws.

13. Certificates

ISO 9001:2015
ISO 13485:2016

CE 1984

Notified Body

Kiwa Belgelendirme
Hizmetleri A.Ş. İTOSB 9. Cd.
No:15 Tuzla / İstanbul / Türkiye

14. Electromagnetic compatibility (EMC) declaration

This equipment generates, uses and can radiate radio frequency (RF) energy. This equipment may cause electromagnetic interference if it is not installed and used in accordance with the manual.This device has been tested for Medical Products in accordance with EN-60601-1-2:2015 and has been determined to comply with acceptable limits. These limits indicate that the device provides an acceptable level of protection against electromagnetic interference (EMC) if the device is used as specified in the manual.This device may be affected by portable and mobile RF communication devices. This equipment must not be stored together with other equipment.See the following tables for more information about this device and EMC.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
Emissions RF CISPR 11	Group 1	The device 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.
Emissions RF CISPR 11	Class B	The device 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.
Harmonic emissions used fordomestic purposes. IEC 61000-3-2	Class A	
Voltage fluctuations/ flickeremissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.

Immunity test	IEC 60601 Testlevel	Compliancelevel	Electromagnetic environment – guidance
Electrostatic discharges IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV,±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV,±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30
Electrical fast transient/burst IEC 61000-4-4	Power supplylines: ±2 kV Input/output lines:±1 kV 100 kHz repetitionfrequency	Power supplylines: ±2 kV Input/output lines:±1 kV 100 kHz repetitionfrequency	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-line IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges Line-to-ground IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV	
Voltage dips IEC 61000-4-11	0% UT;0.5 cycle 0º, 45 °, 90 °, 135 °, 180 °,225 °, 270 ° and 315 °	0% UT;0.5 cycle 0º, 45 °, 90 °, 135 °, 180 °,225 °, 270 ° and 315 °	Mains power quality should be that of a typical commercial or hospital environment.
	0% UT; 1 cycle and 70% UT;25/30 cycle Single phase: 0º	0% UT; 1 cycle and 70% UT;25/30 cycle Single phase: 0º	
Voltage interruptions IEC 61000-4-11	0% UT;250/300 cycle	0% UT;250/300 cycle	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Not: UT is the a.c. mains voltage prior to application of the test level.			
Conduced RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	150kHz to 80MHz: 3Vrms 6 Vrms (in ISM and amateur radio bands) 80% Am at 1kHz 10V/m 80% Am at 1kHz	150kHz to 80MHz: 3Vrms 6 Vrms (in ISM and amateur radio bands) 80% Am at 1kHz 10V/m 80% Am at 1kHz	Portable and mobile RF communications equipmentshould be used no closer to any part ofthe device including cables, than the recommendedseparation distance calculated from theequation applicable to the frequency the transmitter.Recommended separation distance: d= 0.35√ d= 1.2√ 80 MHz ile 800 MHz d= 1.2√ 800 MHz ile 2.7 GHz d= 2.3√ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, asdetermined by an electromagnetic site survey, should be less than the compliance level in each frequency range.Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures,objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio,AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
c. Calibration for current injection clamps shall be performed in a 150 Ω system.
d. If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
e. Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)			
	150 kHz to 80 MHz (out ISM and amateur radio bands) d= 1.2 √ P	150 kHz to 80 MHz (out ISM and amateur radio bands) d= 0.6 √ P	80 MHz to 800 MHz d= 1.2 √ P	800 MHz to 2.7 GHz d= 2.3 √ P
0,01	0,12	0,06	0,12	0,23
0,1	0,38	0,19	0,38	0,73
1	1,2	0,6	1,2	2,3
10	3,8	1,9	3,8	7,3
100	12	6	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W)according to the transmitter manufacture
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17
MHz,21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures,objects and people.

Radiated RF	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modu-lation b) (W)	Distance (m)	Immunity Test Level(V/m)
IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communica-tions equipments	385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380-390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710 745 780	704-787	LTE BANDI 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	810 870 930	800-960	GSM 800/900, TETRA 800, İDEN 820, LTE Bant 5	Pulse modulation b) 18 Hz	2	0,3	28
	1720 1845 1970	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Bant1,3,4,25, UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	2450	2400-2570	Bluetooth,WLAN 802.11b/g/n, RFID 2450,LTE Bant 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240 5240 5785	5100-5800	WLAN 802.11a/n	Pulse modulation b) 217 Hz	0,2	0,3	9

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a. For some services, only the uplink frequencies are included.
b. The carrier shall be modulated using a 50 % duty cycle square wave signal.
c. As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:
E= 6 / d √ P
Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

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