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ESCHMANN

VPX35 & VPX45 Advanced Portable Suction

User Manual

UK
CA
0086

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Please read the manual before using the product for the first time. Keep the manual handy for quick reference. Always make sure that the manual is available for the next user/owner of the product.

The product(s) described by this manual must only be operated and used by medically qualified personnel trained in the use of this equipment. Contact Eschmann with your training requirements.

Pay particular attention to the safety notes, cautions and warnings provided in the text, and also to those displayed on the product labels.

This product must be used and serviced in accordance with the procedures given in this manual. Failure to do so could result in injury to patients and/or users, or damage to the equipment.

The product must be serviced, at least, annually. Eschmann products must be serviced and maintained by Eschmann trained engineers only. Failure to do so may invalidate the warranty.

Contents

1. Usability

Intended User	The VPX35 and VPX45 must only be operated and used by medically qualified personnel trained in the use of this equipment and adhering to the procedures provided in this manual. Operators should be aware of the potential risks of 'Cross Contamination' and 'Biological Contamination' whilst using them. All users should be familiar with the procedures for dealing with and disposing of potentially contaminated components and liquids.
Medical Purpose	The device provides the medical team with a method of evacuating fluids from the patient. Subsequent collection of the fluid makes it possible to conduct analysis or disposal. The unit is fitted with filters to prevent fluid from entering the unit should the collection jars overflow.
Contraindications	Mindful of the warnings and cautions prescribed within this manual, suctioning is a necessary procedure for patients, for example where patients are unable to maintain a patient airway. As determined by medically qualified personnel the conditions or factors that serve as a reason to use or withhold a certain medical treatment are relative to the risks of a worsening clinical condition. There is no absolute contraindication to suctioning as the benefits almost always outweigh the risk to the patient.
Patient Population	The VPX35 and VPX45 can be used irrespective of a patient's details, for example; weight and height. Care should be taken when using suction on a child. The vacuum should be adjusted to take into account the type of procedure and the size of the patient.
Device Use	The device is intended to be used with cannulas and other surgical accessories; the unit itself does not contact the patient. The device is compatible with Collection Jars and single use Disposable Liners, which are sold separately. Refer to manufacturer's Instructions. The handle of the unit is contacted when the unit is moved, the power switch and suction flow control is also contacted when required. The Collection Jars, Filters and Intermediate Tube will be contacted by the user. Note: The Collection Jars and Disposable Liners come into contact with bodily fluids which are not intended to be reintroduced into the body.
Device Application	Environment: The VPX35 is ideally suited for emergency and general use throughout the hospital. The VPX45 is intended for use in the operating theatre and throughout the hospital. The Suction Units are NOT suitable for use in an MRI environment. The Suction Units are NOT intended for field and transport use. The Suction Units are NOT approved for use in Pharyngeal procedures. The Suction Units are NOT suitable for use in the presence of a flammable anaesthetic mixture with Air or with Oxygen or Nitrous Oxide (The devices are not rated as AP or APG). Frequency of use: The Suction Units should not be used for continuous drainage of body cavities although the pump is rated for continuous operation. Mobility: These units are mobile surgical suction devices, operated from the mains electrical supply.
Device Classification	Suction units are non-surgically invasive active devices, intended to remove body fluids or other substances from the body, hence are Class IIa devices, derived from the UK Medical Devices Regulations 2002 (SI 618), as amended by the EU Exit Regulations 2019 (SI 791) and 2020 (SI 1478).
Frequently used functions	• On/off switch • Vacuum gauge display • Vacuum regulator • Handle used for transporting unit • Separately supplied collection jars to be cleaned and sterilised. • Separately supplied single use Disposable Liners to be disposed of. • Hydrophobic Bacterial Filter and Intermediate Tube Assembly to be disposed of. • The Hydrophobic Bacterial Filter and Intermediate Tube should be changed daily, or immediately if the filter becomes wetted or contaminated.

2. Introduction

All users and operators should be made aware of warnings and cautions and comply with them at all times.

Ensure you read the Safety Instructions (Section 2.3) to avoid creating dangerous situations.

⚠ WARNING!
In order to function, the unit must always be connected to a suitable power source.

⚠ WARNING!
To enable mains isolation: Do not position the unit such that it is difficult to disconnect the mains plug from the power source.

⚠ CAUTION
No components in this unit can be serviced or maintained whilst the unit is in use.

2.1. Technical Lifetime

This product has a technical lifetime of 7 years. At the time of delivery the product fulfils the existing regulations and standards but as with all other electro-mechanical products, the Eschmann VPX35/ VPX45 is subject to ageing and wear, and even though the product may have undergone regular service in accordance with the recommended device schedule, Eschmann cannot guarantee the product's safety after the expiry of the technical lifetime.

Provision of spare parts and service by Eschmann after the expiry of the specified technical lifetime does not mean an extension of Eschmann Technologies Limited liabilities.

2.2. Product Liability

All liability in respect of the functioning of the Suction Unit will rest with the user if:

- The unit is used for other than its true intended purpose.
- The unit is not used in accordance with this User Manual.
- The unit is opened by, or assembled, maintained or repaired by personnel who have not been fully trained by Eschmann.

CAUTION
Reduced safety from using incorrect accessories. The use of accessories which have not been recommended by Eschmann may impair the safety and functioning of the equipment. All question of any guarantee is excluded if damage arises from the use of non-recommended accessories or from improper use. Only use original accessories recommended by Eschmann.

⚠ WARNING!
To avoid risk of electric shock, this equipment must only be connected to a mains supply with a protective earth.

⚠ WARNING!
Risk to patients and staff from improper use.

Never use a unit for other than its intended purpose.

Eschmann are not responsible for any malfunction in the unit if it is not used as specified.

Never use the unit for long term suction, such as the drainage of body cavities.

No modification of the equipment is allowed.

2.3. Safety Instructions ⚠

- Various warnings, cautions and notes are made throughout this manual. Each of these carries a special meaning and should be read carefully.
- A WARNING is given when the safety of the patient or user may be involved. Disregarding this information could result in injury to the patient or user.
- A CAUTION is given when special instructions must be followed. Disregarding this information could result in permanent damage to the product.
- A NOTE provides specific information that makes important instructions clear.
- The following safety instructions should be observed when operating the Suction Unit:
- Use the Suction Unit only on a horizontal floor or surface.
- Do not leave the Suction Unit in a 'traffic' area.
- Ensure lockable castors are 'locked' when the Suction Unit is in use.
- If liquid or solid matter is drawn into the pump, the unit must be withdrawn from use due to potential contamination. Please contact your local authorised Eschmann service engineer.
- A new Disposable Liner and Suction Tube (Between Disposable Liner Lid and patient) to be used for each patient.
- The Hydrophobic Bacterial Filter and Intermediate Tube should be replaced daily unless:

  a) The Hydrophobic Bacterial Filter becomes wetted or contaminated.

  b) Local or internal guidelines referring to more progressive forms of contamination require it to be changed following a particular patient procedure.
- Clean and sterilise jars in accordance with manufacturer's instructions.
- If the vacuum reading or suction rate is too low, do not continue to use the Suction Unit until this has been rectified.
- Do not obstruct or cover ventilation holes on the Suction Unit.

- Do not leave part filled Disposable Liners/ jars in the Suction Unit overnight. The Liners should be disposed of in accordance with manufacturer's instructions.
- Do not overfill Disposable Liners/ jars. Liners should be replaced in accordance with manufacturer's instructions.
- Always have a stock of Eschmann approved spares and accessories to hand. See Appendix 3 for a list of parts.
- Avoid getting moisture on the mains inlet, the plug or the switch.
- Never dip the equipment into water or other liquids (even when switched off).
- Keep the Suction Unit and cable well away from sources of heat.

⚠ WARNING!
Any potentially contaminated waste materials produced during use should be disposed of safely and carefully, taking into account any National, Local or Hospital procedures which cover the disposal of potentially contaminated liquid or solid waste.

⚠ WARNING!
Risk of damage from using the wrong electricity supply.

Improper use may lead to excess voltage in the equipment which may transfer to the user.

Before using the equipment for the first time, ensure that the mains supply is correct for the supply shown on the serial label on the back of the unit.

2.4. Symbols

Symbol	Meaning
⚠ or ⚠	Refer to warnings and cautions in manual
	Refer to instructions in user manual
	Follow disposal regulations in the country of use (WEEE directive symbol for Waste Electrical and Electronic Equipment)
	Fuse
SN	Serial number
REF	Catalogue reference
	Date of manufacture
	Manufacturer
	Single use only, do not reuse
	Use on alternating current only
	Vacuum is increased by clockwise rotation of this control
	Patient connection side of Hydrophobic Bacterial Filter
	Footswitch
UK CA 0086	The UKCA marking of the product certifies that it complies with the Medical Devices Regulations 2002 (SI 618), as amended by the EU Exit Regulations 2019 (SI 791) and 2020 (SI 1478)

2.5. Compatibility of Materials

⚠ WARNING!
Never use disinfectants which contain acetone. They may lead to damage or spoil the plastic parts of the casing.

⚠ WARNING!
Aggressive substances may damage both the Suction Unit and accessories. Follow the notes on cleaning in Section 4.

3. Instruction for Use

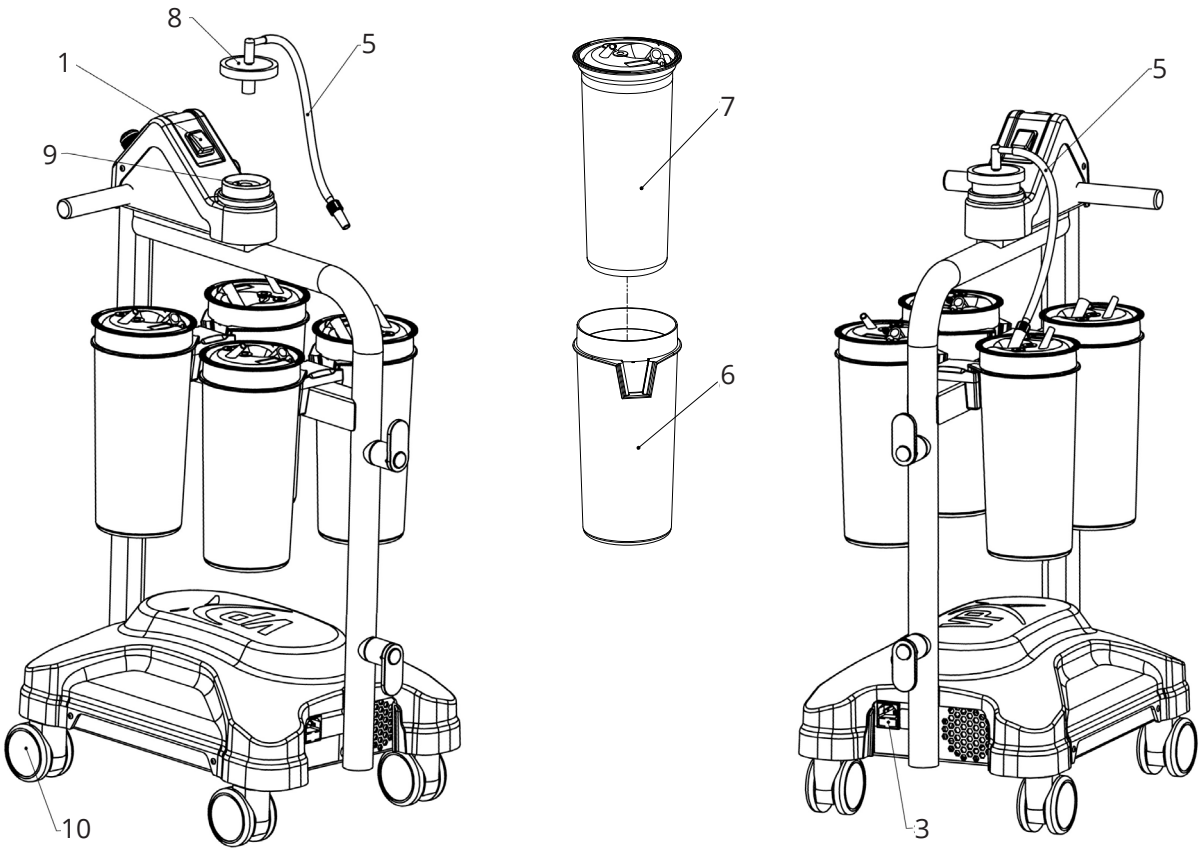
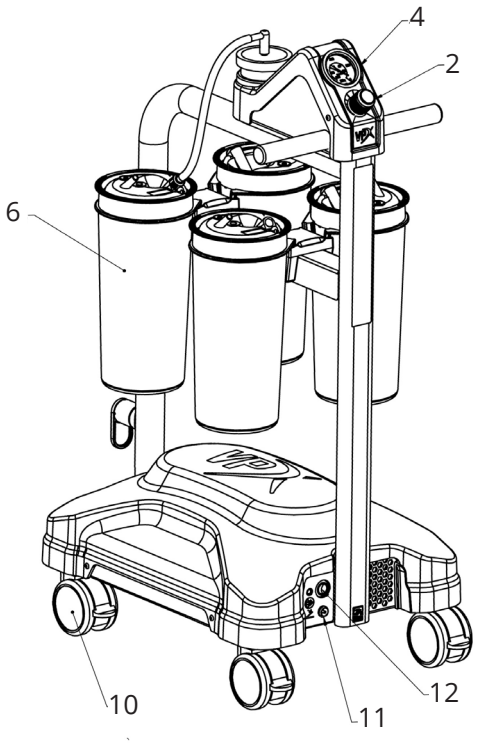


Fig 1: VPX35/VPX45 Suction Unit

1 = 'On' / 'Off' Switch
2 = Vacuum Control Knob
3 = Mains Inlet
4 = Vacuum Gauge
5 = Intermediate Tube Assembly
6 = Jar (Sold separately)
7 = Disposable Liner (Sold separately)
8 = Hydrophobic Bacterial Filter
9 = Filter Mounting Block
10 = Lockable Castor (x 4)
11 = Footswitch Connection
12 = Footswitch Override



3.1. Introduction

The Eschmann VPX35 and VPX45 Suction Units are mobile, mains powered surgical Suction Units for the removal of fluids from patients.

The basic product, as supplied, comprises a Suction Unit, Hydrophobic Bacterial Filter and Intermediate Tube Assembly.

The Suction Unit is compatible with separately supplied collection jars and Disposable Liners. (Collection Jars and Disposable Liners are covered by separate manufacturer's Instructions).

Suction Tubing between a Disposable Liner and patient is not supplied by Eschmann and is the responsibility of the user.

When the unit is fully connected up and switched on, the vacuum pump produces a vacuum in the Intermediate Tube (5) and fitted, compatible Jar (6)/ Disposable Liner (7), which exert suction on patient body fluids via a user supplied Suction Tube.

The Liquids are drawn and collected into a compatible Jar/ Disposable Liner. The fitted Jar / Liner should be monitored and replaced in accordance with manufacturer's instructions. Compatible Disposable Liners incorporate an overflow valve in the lid which shuts off the vacuum if the maximum fluid level is exceeded.

The suction level is set by means of the vacuum control knob.

The unit may be footswitch enabled by the factory. These units can be operated by a footswitch connected to the unit

A safety cut out at high temperatures prevents overheating of the Suction Unit and ensures that it switches off automatically.

Note: All accessories should be used in line with their instructions, where supplied.

Note: The four castors on the unit each have wheel protectors (two per castor). After unpacking, and before first use, remove the wheel protectors by firmly pulling the tab at the centre of each side of the castors until the protectors come off.

3.2. Deliverables

The following items are delivered:

- Suction Unit
- User Manual
- Mains cable
- Intermediate Tube Assembly
- Hydrophobic Bacterial Filters
- Footswitch and hose (optional)

The following items are compatible with the VPX35 & VPX45 but sold separately. (Refer to Appendix 3).

- Collection Jars
- Disposable Liners

The following item is supplied by the user:

- Suction Tube (To patient)

3.3. Pre Use Checks and Set Up

Note: The Suction Unit must only be operated and used by fully trained staff.

Note: Before using the Suction Unit for the first time, please familiarise yourself with these instructions and how the unit works.

To ensure the Suction Unit operates efficiently, the following checks should be performed prior to each procedure:

1. Ensure the VPX35 or VPX45 is clean.
2. Inspect the pump casing for damage.
3. Check the mains lead prior to connection to the unit or power source. Check the plug, and the entire length of the cable for damage. Change the mains lead **immediately** if any damage is found. An Eschmann mains lead will be supplied with the unit and **must** be used with the unit.
4. Plug the mains lead into the unit and ensure the connection is not loose or likely to fall out of the mains inlet socket (3) during use.
5. Check that the locking casters (10) function as expected, and that when unlocked all castors are free running.
6. Refer to manufacturer's Instructions for pre use checks and set up applicable to compatible Collection Jars and Disposable Liners.
7. Inspect the Collection Jars and Intermediate Tube for any damage.
8. Ensure that a Disposable Suction Liner is fitted to a Collection Jar in accordance with manufacturer's instructions.
9. Ensure that the Intermediate Tube is connected from the Hydrophobic Bacterial Filter elbow connection to a compatible Disposable Suction Liner vacuum port using the Taper Connector.
10. Inspect the Vacuum Gauge (4) and Vacuum Control Knob (2).
11. Where applicable check the Footswitch for damage.
12. Ensure a Hydrophobic Bacterial Filter (8) is fitted.
13. Plug the mains lead into a power source.
14. Turn the unit to 'On'. Check the 'On / Off' switch (1) is illuminated when in the 'On' position.
15. Check the pump is now running. If a Footswitch is in use, the Footswitch will need to be pressed to activate the pump. This is a latching system such that the pump will continue to operate when the footswitch is released. If the footswitch is pressed again the pump will cease to operate.

⚠ WARNING!
If the Suction Unit is footswitch enabled, it is possible for the pump to be disabled even when mains power is applied. In this circumstance the orange "footswitch override" light will be illuminated.

16. To re-enable the pump, should the footswitch be unavailable, use the footswitch override (13). Once the pump is running again, the override light will no longer be illuminated.
17. Check the suction performance of the unit. Turn the vacuum control knob (2) fully clockwise. This will give maximum vacuum. Blank off the suction either at the filter or at the jar. The vacuum gauge (4) should rise to a reading of at least 660mmHg (-88kPag) or above for the VPX35 or 720mmHg (-96kPag) for the VPX45.

Note: A stock of Eschmann accessories and spares should always be available.

3.4. Setting the Required Vacuum

Once switched on, set the required vacuum by placing a finger over the inlet nozzle of the compatible Liner lid to which the Intermediate Tube (5) is connected. Turn the vacuum control knob (2) clockwise to increase the suction or anti-clockwise to decrease the suction until the desired vacuum is indicated on the Vacuum Gauge (4).

When the suction is applied to the patient, if a different vacuum is required, turn the vacuum control knob (2) clockwise to increase or anti-clockwise to decrease the vacuum, as required.

Once the unit is no longer required, switch it off using the 'On / Off' switch (1).

Note: The VPX35 or VPX45 may be Footswitch enabled. This is a latching system such that the pump will continue to operate when the footswitch is released with the mains switched to the 'On' position. If the Footswitch is pressed again the pump will cease to operate.

3.5. Fitting/Removing the Jar and Disposable Liner

⚠ WARNING!
Risk to health from dealing with infectious or pathogenic organisms.

⚠ CAUTION

Switch the Suction Unit off before removing or replacing Collection Jars or Disposable Liners.

To fit or remove compatible Jars and Disposable Liners, refer to the manufacturer's Instructions.

⚠ WARNING!
Any potentially contaminated waste materials produced during use should be disposed of safely and carefully, taking into account any National, Local or Hospital procedures which cover the disposal of potentially contaminated liquid, solid or waste.

3.6. Overfill Protection

Do not overfill Collection Containers. Disposable Liners should be changed in accordance with manufacturer's instructions.

Overfill protection is built into the lid of compatible Disposable Liners. Refer to the Disposable Liners manufacturer's Instructions.

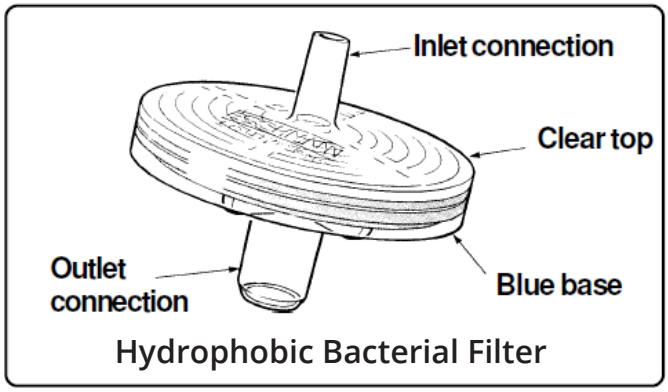
3.7. Replacing the Hydrophobic Bacterial Filter

⚠ CAUTION

DO NOT use substitutes for the specified Hydrophobic Bacterial Filter. See parts list in Appendix 3

Change the Hydrophobic Bacterial Filter daily

Change the Hydrophobic Bacterial Filter immediately if it becomes wet or contaminated



Hydrophobic Bacterial Filter

The Hydrophobic Bacterial Filter is designed to protect the pump from contamination and should be replaced daily unless:

a) The Hydrophobic Bacterial Filter becomes wetted or contaminated.

b) Local or internal guidelines referring to more progressive forms of contamination require it to be changed following a particular patient procedure.

To replace the Hydrophobic Bacterial Filter, remove the Intermediate Tube from the elbow fitting at the inlet side of the filter. Remove the filter and elbow fitting from the filter mounting block by carefully pulling the filter upwards. Take a new filter and insert the filter outlet connection into the filter mounting block by gently pushing the filter down. Ensure the filter is fully seated in the mounting and is the right way around (See illustration above). Fit a new elbow to the filter inlet connection (Elbow supplied with the filter). Reconnect the intermediate tube to the new elbow fitting.

3.8. Replacing the Intermediate Tube Assembly

⚠ CAUTION

Change the Intermediate Tube daily

Change the Intermediate Tube immediately if the Hydrophobic Bacterial Filter becomes wet or contaminated

The Intermediate tube should be replaced Daily unless:

a) The Hydrophobic Bacterial Filter becomes wetted or contaminated.

b) local or internal guidelines referring to more progressive forms of contamination require it to be changed following a particular patient procedure.

Remove the intermediate Tube Assembly (Comprising the Intermediate Tube and Taper Connector), which is connected from the Hydrophobic Bacterial Filter (8) to the Disposable Liner lid.

Take a new Intermediate Tube Assembly and fit to the Hydrophobic Bacterial Filter by attaching the free end to the elbow fitting. Connect the Taper Connector, attached at the other end of the Intermediate Tube, to the connector labelled "Vacuum" on the Disposable Liner lid.

3.9. Using a Footswitch

Use only the Eschmann approved Footswitch (see appendix 3 for part number).

Note: A Footswitch can only be fitted to a unit that has been footswitch enabled from the factory.

Connect the end of the Footswitch hose to the Footswitch connection (12).

When the unit is switched on, activating the Footswitch will switch the pump on and off.

⚠ WARNING!

If the Suction Unit is Footswitch enabled, it is possible for the pump to be disabled even when mains power is applied. In this circumstance the orange "Footswitch override" light will be illuminated.

To re-enable the pump when the Footswitch is unavailable, use the Footswitch override (13).

4. Maintenance

⚠ WARNING!
Risk to health from dealing with infectious or pathogenic organisms.

Any germs and pathogens in body fluids may cause damage to health.

Check the external filter is dry and clean before every use to ensure faultless functioning.

Always aspirate by means of a catheter. The suction tube must never come into direct contact with the body part.

Follow the notes on cleaning exactly.

Ensure that the Suction Unit is serviced and checked for safety, at least, on an annual basis. All servicing and maintenance procedures should be carried out by engineers who have been trained by Eschmann. Training, a service, or a service contract can be arranged through the Eschmann Customer Service Department. Eschmann can provide a service manual, which includes drawings, diagrams, descriptions and instructions to enable service and repair of the equipment by Eschmann trained engineers.

⚠ CAUTION
If maintenance is neglected, suction performance could be found inadequate in an emergency situation. It is also recommended that if placed on standby for emergency duty, the unit is tested by switching on at regular intervals.

4.1. After Each Day's Use

The following should be carried out daily, immediately after use once the unit is unplugged from the mains supply:

1. Remove the Hydrophobic Bacterial Filter, elbow and the Intermediate Tube Assembly.
2. Clean the unit and all reusable components likely to be in contact with aspirated body fluids. See 4.2 for details.
3. Clean and sterilise the Collection Jars. Refer to manufacturer's instructions.
4. Footswitch (optional): clean by immersion in hot (55 °C) neutral (pH7) detergent solution (diluted in accordance with the manufacturer's instructions), rinse with clean water and wipe dry.

4.2. Disinfecting and Cleaning the Unit

Refer to Section 2.5 'Compatibility of Materials'.

⚠ WARNING!
Unplug the unit from the main supply before cleaning or disinfecting.

⚠ WARNING!
It is recommended that you always wear suitable disposable gloves during disinfection procedures.

Note: Cleaning and disinfecting should be performed at the end of each day. However, it is recommended that the unit be wiped down after every procedure with a detergent wipe or anti-bacterial wipe/solution.

1. Move the Suction Unit to a well-ventilated area and one used as a disinfection area.
2. Wash the outside of the Suction Unit with a hot (55 °C) neutral (pH7) detergent solution (diluted in accordance with the manufacturer's instructions), taking care to not allow any solution to enter the unit through the vent holes. Rinse with clean water and wipe dry.
3. Disinfect the unit by washing down all the surfaces and crevices with a 70% solution of industrial methylated spirit and water and allow them to dry by evaporation at room temperature.

4.3. Sterilising the Jars

Refer to manufacturer's instructions.

5. Troubleshooting

Fault	Possible Cause	Remedy
Total loss of suction	1. Disconnection in intermediate tube. 2. Overflow protection operated. 3. Disposable filter blocked.	1. Reconnect intermediate tube. 2. Switch to new Disposable Liner or Jar. 3. Replace filter **immediately.**
Partial loss of suction	1. Split or damaged Disposable Liner. 2. Filter wetted or fouled. 3. Cracks or chips in jar.	1. Replace Disposable Liner. 2. Replace filter **immediately.** 3. Replace Jar.
Vacuum gauge – no indication	1. Loss of vacuum.	1. See 'Total loss of suction' and 'Partial loss of suction' above.
No power	1. Mains lead disconnected. 2. Failed fuse in mains plug or unit. 3. Break in mains supply cable. 4. Footswitch has turned off unit (footswitch override light illuminated).	1. Reconnect mains lead. 2. Check/replace fuse. 3. Replace mains supply cable. 4. Activate footswitch or footswitch override.

A thermal overload switch, which is self-resetting, is incorporated to protect the pump in the event of a seizure or excessive running temperatures. Should the pump stop it is essential to disconnect the electrical supply to the unit before attempting any form of maintenance. Any maintenance should be carried out by a trained Eschmann Service Engineer, or an Eschmann trained third party Engineer.

6. Disposal

6.1. Waste Electrical & Electronic Equipment (WEEE) Regulations

The aim of the WEEE Regulations is to reduce the amount of waste going into landfill.

All Eschmann products that must be recycled in accordance with the WEEE Regulations are marked with the 'wheelie bin' symbol opposite.

Please contact Eschmann when one of our products, marked with the symbol, reaches the end of its working life. We will be able to advise on how to recycle and dispose of the product correctly.

Note: If we request that the product is returned to Eschmann, it must be decontaminated first. We will request a certificate.

Under the WEEE Regulations, manufacturers are held responsible for recycling waste electrical and electronic equipment (WEEE) placed on the market after 13 August 2005 that has reached the end of its working life. The regulations also place obligations to comply on distributors, retailers and end users of the equipment.

Appendix 1. Technical Data

Feature	VPX35	VPX45
Connectivity	Up to 4 Disposable Liner System Jars	Up to 4 Disposable Liner System Jars
Maximum jar capacity	2000ml per jar	2000ml per jar
Intermediate Tube	6.35mm inner diameter	6.35mm inner diameter
Nominal mains voltage	230V	230V
Mains frequency	50Hz and 60Hz models	50Hz and 60Hz models
Power consumption	115 Watts	130 Watts
Filter	Hydrophobic bacterial	Hydrophobic bacterial
Pump type	2-headed diaphragm pump	4-headed diaphragm pump
Pump performance	Airflow rate: >35 litres/min Vacuum: 660 to 680 mmHg (-88 to -91 kPag)	Airflow rate: >44 litres/min Vacuum: 720 to 740 mmHg (-96 to -99 kPag)
Classification (BS EN 10079-1)	High vacuum/ High flow rate	High vacuum/ High flow rate
Duty cycle	Continuous	Continuous
Dimensions (unit only)	360mm (w) x 500mm (l) x 880mm (h)	360mm (w) x 500mm (l) x 880mm (h)
Weight	10.25kg (bare unit)	10.5kg (bare unit)
Noise level	<59dB	<57dB
Protection Class (IEC 60601-1)	Class 1	Class 1
Class of risk	Class IIA	Class IIA
Operating Conditions	Operating temperature: 5°C to 40°C Pressure: 69kPa to 106kPa Humidity: 30% to 75% RH non-condensing	Operating temperature: 5°C to 40°C Pressure: 69kPa to 106kPa Humidity: 30% to 75% RH non-condensing
Storage and Transport Environment	Operating temperature: -30°C to 50°C Pressure: 69kPa to 106kPa Humidity: 30% to 90% RH non-condensing	Operating temperature: -30°C to 50°C Pressure: 69kPa to 106kPa Humidity: 30% to 90% RH non-condensing
Net weight	15.5kg	16kg
Gross weight	25kg	25.5kg
Export case dimensions	510mm (w) x 720mm (l) x 980mm (h)	510mm (w) x 720mm (l) x 980mm (h)
Ingress Protection	IPX0	IPX0

Products are not produced with natural rubber latex.

Appendix 2. EMC Information

Installation

As with all medical electrical equipment, care should be taken with regard to electromagnetic compatibility (EMC). These instructions for the VPX35 and VPX45 are written in line with the latest international standards (EN60601-1-2) and are designed to minimise the risk of electromagnetic compatibility issues.

The VPX35 and VPX45 pumps should be put into service in accordance with the EMC information provided below.

⚠ WARNING!

RF communications equipment:

As with any other electro-medical device the user should be aware that portable and mobile RF communications equipment can affect medical electrical equipment.

Accessories:

As with all medical electrical equipment, and in line with the latest international standards (EN60601-1-2) the user should be warned that the use of accessories, transducers and cables other than those specified below (with the exception of those sold by Eschmann Equipment as replacement parts for internal components) may result in increased emissions or decreased immunity of the VPX35 and VPX45 pumps and their associated accessories.

Only Eschmann Equipment mains leads can be used with VPX35 and VPX45 without affecting the unit's electromagnetic compatibility with sub clauses 6.1 and 6.2 of EN60601-1-2.

Other mains leads or equivalents that could affect compliance with the requirements of sub-clauses 6.1 and 6.2 of EN60601-1-2 should not be used.

Refer to Appendix 3 for replacement mains lead part number.

Filters, jars, Liners and tubing are designed for use with the VPX35 and VPX45 pumps and have no EMC implications.

⚠ WARNING!

Installation:

The VPX35 and VPX45 pumps have been tested for use in close proximity with other equipment. They should not be used stacked with other equipment without observation to verify normal operation in the configuration in which they will be used.

It should be noted that, though the risks of electrical interference to and from other devices normally used in conjunction with this product have been taken into account during testing, it is not possible to simulate all conditions that maybe encountered. Therefore, the compliance testing provides only a very good indication as to susceptibility or suppression of emissions to and from the device.

EMC Tables

The following guidance is provided in line with EN60601-1-2. Refer to tables 1 and 2.

Table 1 - Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The VPX35 and VPX45 pumps are intended for use in the electromagnetic environment specified below. The customer or user of these pumps should assure that it is used in such an environment. VPX35 and VPX45 pumps have been tested in accordance with the limits, methods of measurement and provisions of CISPR 11. The pumps are classified Group 1, Class A.		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
Mains terminal disturbance voltages CISPR-16-2-1	Complies	The VPX35 and VPX45 pumps use RF energy only for their internal function, therefore, RF emissions are low and are not likely to cause interference in nearby electronic equipment. The VPX35 and VPX45 are intended for use in a hospital environment. The VPX35 and VPX45 are NOT suitable for use in an MRI environment.
Electromagnetic radiation disturbances-Electric field CISPR-16-2-3	Complies	
Harmonic current emissions IEC 61000-3-2	Complies	
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

The emissions characteristics of this equipment make them suitable for use in industrial areas and hospitals (CISPR 11 class A). If used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 2 - Essential Performance

Essential Performance: VPX35	Essential Performance: VPX45
Vacuum supplied, when regulator is set to maximum, must be within the following range: 450mmHg to 680mmHg (-60 to -91kPag) when tested as per ISO 10079-1	Vacuum supplied, when regulator is set to maximum, must be within the following range: 450mmHg to 740mmHg (-60 to -99kPag) when tested as per ISO 10079-1
Flow rate supplied, when regulator is set to maximum, must be within the following range: 20 litres/ min to 48 litres/ min (free air flow) when tested as per ISO 10079-1	Flow rate supplied, when regulator is set to maximum, must be within the following range: 20 litres/ min to 55 litres/ min (free air flow) when tested as per ISO 10079-1
In single fault mode, excessive flow or vacuum pressure must not be allowed to develop. Max 48 litres/min and 680mmHg (-91kPag)	In single fault mode, excessive flow or vacuum pressure must not be allowed to develop. Max 55 litres/min and 740mmHg (-99kPag)
In single fault mode, reverse flow (i.e. positive pressure) must not be allowed to be developed	

Appendix 3. Accessories and Spares

REF/ Part No.	Part Name
8292361	2 litre jar standard Disposable Liner System
8292357	Standard (8.5mm) 2 litre Liners for standard Disposable Liner System (Box of 30)
8296185	Sealed, disposable Hydrophobic Bacterial Filters for VPX35 and VPX45 series (Pack of 10)
8260021	Pneumatic Footswitch, white, with 5 meter tube
714188	Mains Lead (UK) 4m orange
216138	Intermediate Tube Assembly (Pack of 10)

Service

Eschmann products are supported by a network of fully trained engineers, offering high quality Eschmann spare parts. For further information on the range of Service Contracts available, please contact your local Eschmann representative.

Eschmann can be contacted during normal office hours. Please quote the Model and identifying numbers (SN) exactly as printed on the product label. Address all Eschmann correspondence to:

Eschmann Technologies Limited, Eschmann House, 15 Peter Road, Lancing, West Sussex, BN15 8TJ, United Kingdom. Tel: +44 (0)1903 753322

Safety Reporting

Any serious incident that occurs with this medical device should be reported to Eschmann Technologies Limited and your local Competent Authority.

Warranty

This product and purchased accessories are warranted for a minimum period of 12 months to be free from defects in materials and workmanship at the time of delivery.

Eschmann will be under no liability for any defect arising from fair wear and tear, negligence, wilful damage, misuse, abnormal working conditions, failure to follow the manufacturer's instructions, unauthorised alteration or repair of hardware, unauthorised or accidental alteration of software or configuration, lost profits, commercial loss, economic loss, or loss arising from personal injury. We may, at our discretion, raise a charge for any faults repaired that fall outside the warranty cover. Where charges are necessary, replacement parts will be charged at manufacturers' list prices and labour will be charged at the prevailing hourly rate. Repairs performed by Eschmann carry a 3-month parts and labour warranty.

The details in this manual are correct at time of going to press and supersede details previously published elsewhere. Information, technical specifications and statements made in this publication may be subject to change without prior notice. The Company reserves the right to modify or improve the product referred to.

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