VACUUM PUMP

Vacuum Pump User Manual

Please familiarise yourself with the safety instructions before using the device.
Federal Law(USA) restricts this device to use by or on the order of a physician.

COOK® MEDICAL

General Information

WARNING:
READ THIS MANUAL.
Please familiarise yourself with the contents of the manual before using the device. Failure to comply with these instructions may result in damage to device, device contents, and/or patient or user injury. This device should only be used by qualified personnel.

WARNING:
ELECTRIC SHOCK HAZARD.
The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements.

WARNING:
Any adjustment, modification or repairs to the equipment should be carried out by persons authorised to perform them.

Disposal of this product must be undertaken with regard to the WEEE directive (2002/96/EC).

Copyright

Users of William A. Cook Australia Pty. Ltd. products should not hesitate to contact us if there are any unclear points or ambiguities in this manual.

This symbol indicates that this product may not be treated as municipal waste. Please ensure that this product is properly disposed of as inappropriate waste handling of this product may cause potential hazards to the environment and human health. For more detailed information about disposal of this product, please contact your local city office or Cook Medical Representative.

Document No: IFU-MAR52_US-1

Service address:

Please refer to your local Cook Medical distributor for details of your nearest authorised service agent.

Table of Contents

Explanation of Pictograms

The following pictograms appear on the Vacuum Pump and the Disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240)

	Before connection, read the manual!
	Refer to IFU – Mandatory
	Standby/On
	Increase Vacuum Set-Point
	Decrease Vacuum Set-Point
	Boost Vacuum
	Patient Tube Connection
	Foot Pedal Connection
	Symbol for type B equipment
	CE – Approval Marking
	UL – Approval Marking
	Dispose of in accordance with WEEE directive (2002/96/EC)
	Manufacturer

EC REP	EC Representative
REF	Catalogue Code
SN	Serial Number
IP41	Degree of enclosure protection from solid objects and liquids
(1) 	Do not reuse
(1) 	Do not use if packaging is damaged
(1) 	Keep away from sunlight
(1) 	Keep dry
(1) LOT	Batch code

Note (1): Symbols are on sterile Disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240) packaging only.

How to use this Manual

Warnings and Important Notes

Throughout these Instructions for Use, blocks of text may be accompanied by a pictogram and/or printed in bold type. These instructions point out special service procedures or precautions that must be followed to avoid damaging the device. These blocks are WARNINGS and IMPORTANT NOTES and they are used as follows:

	WARNING: The personal safety of the patient may be involved. Disregarding this information could result in injury to the operator, device or the contents!
	WARNING: Biological hazard
	WARNING: Electric shock hazard
	WARNING: Explosion hazard
	IMPORTANT NOTE: This provides special information that facilitates maintenance or clarifies important instructions. Please pay particular attention to the Safety Instructions (see §1).

Manual Structure

This manual has a table of contents (page 2) to help you find section titles quickly. Additionally, an index is on page 16. There is a troubleshooting guide on page 15 to help you to trouble shoot problems.

1. Safety Instructions

WARNING: *Please familiarise yourself with the safety instructions before using the Vacuum Pump.*

WARNING: *This Vacuum Pump should only be operated by appropriately qualified personnel.*

IMPORTANT NOTE: *Replacement device and disposables.*

WARNING: BIOLOGICAL HAZARD. *Always use the disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240). Never use the device if there is any indication that the tubing, the filter or the Vacuum Pump is contaminated.*

If the Vacuum Pump is suspected to be contaminated, do not allow further use of the device and immediately notify your authorised service agent to have the device checked and repaired.

The disposable Vacuum Line with Hydrophobic Filter attached to the Vacuum Pump are for single patient use only and must not be re-used or resterilised. Re-use of this device may result in cross-contamination which may lead to the transmission of infectious diseases. Re-sterilisation of this device may compromise the structural integrity of the device and cause product failure. Once used, this product is considered as infectious and should be disposed of according to local policy for disposal of biohazard waste.

WARNING: *Monitor the vacuum.*

WARNING: *Electric shock hazard.*

WARNING: *No user serviceable parts inside.*

EXPLOSION HAZARD: *Device can cause explosion in presence of flammable gases.*

WARNING: *Use only original disposables.*

This manual describes the operation and intended use of the Vacuum Pump and the disposables.

It is essential to use this document to familiarise yourself with the functions and the operation of the Vacuum Pump before use.

Failure to follow these instructions can result in serious injury to the patient or the operating team and can lead to damage or breakdown of the device and disposables.

This manual does not provide a detailed description of operation technologies, nor is it suitable for introducing a beginner to this operating technique. Only physicians and medical assistants under the direction of a physician with the appropriate technical qualification may use this device and disposables.

In case the Vacuum Pump fails during an operation, a replacement device and replacement disposables should be kept within reach so that the operation may be completed.

Always work with the one-way hydrophobic filter between the collection receptacle and the Vacuum Pump to prevent body fluids from entering the device.

Never use the Vacuum Pump if there is any indication that the tube, the filter or the device is contaminated. Do not allow any further use of the device. Immediately notify your authorised service agent to have the device checked and repaired.

Always monitor the aspiration vacuum level. An excessive vacuum can lead to damage of the oocyte or other body tissue.

There is evidence in the published literature suggesting that the use of higher vacuum aspiration pressures (greater than -300 mmHg) can lead to the potential for decreased oocyte quality and, consequently, decreased development and fertilisation potential. For oocyte aspiration, only use the highest vacuum aspiration pressure necessary to achieve the required flow rate for the size aspiration needle being used. The boost should only be used to clear blockages or obstructions in the aspiration line or aspiration needle when the needle is outside the patient.

The Pre-Operation Test (see §3.16) must be performed prior to each operation.

If a Vacuum Pump defect is suspected or confirmed, stop using the device until an authorised service agent has checked it.

Internal circuitry is energised whenever the Vacuum Pump is connected to mains power irrespective of whether the device is on or in standby. Always disconnect the device from mains power before cord replacement, or cleaning. Should any power cord or plug associated with the device become cracked, frayed, broken or damaged it must be replaced immediately.

To reduce the risk of electric shock, do not remove covers. Refer servicing to an authorised service agent.

Protect the Vacuum Pump from being splashed by liquid. Should any liquid enter the device, discontinue use immediately.

Please refer all servicing to the manufacturer's authorised service agent.

Do not use in an area where flammable gases are present.

For your own safety, only use original disposables (see §7).

2. About the K-MAR-5200

2.1 Indications for Use

The Cook Vacuum Pump is intended for the aspiration of eggs (ova), during assisted reproduction procedures using low flow, intermittent vacuum.

2.2 Contraindications

There are no known contraindications for these devices.

2.3 Device Description

The Vacuum Pump is designed to maintain a vacuum accurately at a user specified setting with a range of -10 mmHg to -500 mmHg when configured to display mmHg and a range of -1.0 kPa to -67.0 kPa when configured to display kPa. In either case, the device will maintain the vacuum within ±5 mmHg (0.7 kPa).

The device can also boost the vacuum to -500 mmHg (or -67.0 kPa in kPa display mode) from any setting.

The disposable Vacuum Line with Hydrophobic Filter consists of a one-way hydrophobic filter and 240 cm long low volume vacuum line. The disposable Vacuum Line with Hydrophobic Filter is used to connect ovum aspiration needles to the Cook Vacuum Pump to prevent contamination of the unit. It is supplied sterile in peel-open packages and is intended for single-use.

2.4 Precautions for Device Use

In the event of any electrical or mechanical fault during use or entry of fluid into the Vacuum Pump, cease use of the device until it has been checked by an authorised service agent.

3. Installation and Set-up

IMPORTANT NOTE: *It is important to retain packaging for future use. (Refer to §6.4 - Return Procedure)*

An installation and set-up checklist has been included at the end of this section (see §4). This may be used to help ensure correct preparation.

3.1 Unpacking

Items supplied

Please find the following items supplied:

1

2

3

4

5

1. **User Manual**
2. **Vacuum Pump**
3. **Disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240)**
4. **Foot Pedal**
5. **Power Cord**

Check all items immediately upon receipt to make sure the contents are complete and that nothing is damaged. The manufacturer will only honour claims for compensation which are forwarded immediately to the sales representative or the authorised service agent.

Remove all items from plastic covers except the disposable Vacuum Line with Hydrophobic Filter (item 3) which needs to be handled under sterile conditions.

IMPORTANT NOTE: *Items required that you need to supply are listed here.*

3.2 You Need to Supply

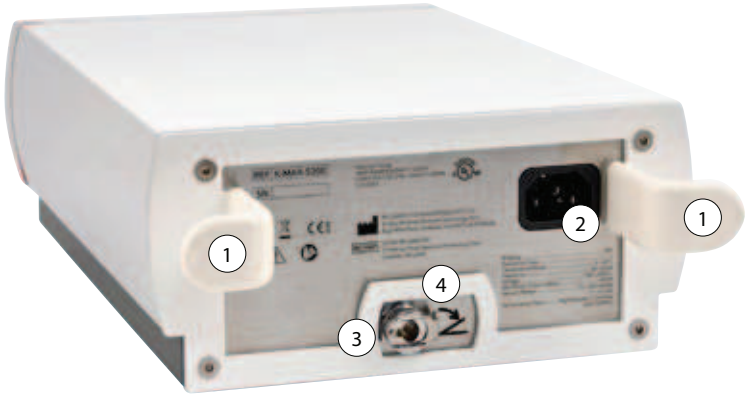
The following items are not supplied:

- Test Tube Heater and test tubes.
- Aspiration Fluid.
- A source of sterile distilled water.

3.3 Front of the Device

1. **Standby Indicator** Indicates the powered on state, Green = Active, Orange = Standby.
2. **Standby Touch-Pad** Toggles the device between Active and Standby State.
3. **Vacuum Display** Displays the measured vacuum.
4. **Vacuum Adjust Indicators** Indicates Set-Point adjustment.
5. **Vacuum Adjust Touch-Pad** Decrease, Press to decrease the Vacuum Set-Point.
6. **Vacuum Adjust Touch-Pad** Increase, Press to increase the Vacuum Set-Point.
7. **Boost Touch-Pad** Press to boost the vacuum to -500 mmHg (-67 kPa).
8. **Boost Indicator** Indicates the Boost Function is active.
9. **mmHg Indicator** Indicates that the display will show the vacuum in mmHg.
10. **kPa Indicator** Indicates that the display will show the vacuum in kPa.
11. **Patient Tube Connection** Barb fitting for connection to the Vacuum Line and Filter.
12. **Vacuum Supplied Indicator** Indicates that vacuum is being supplied.

3.4 Rear of the Device



1. **Power Cord Mount** Used to hold the Power Cord when the device is not in use.
2. **Mains Power Inlet** Connect the appropriate Power Cord to this point.
3. **Foot Pedal Connection** Connect the Foot Pedal to this point.
4. **Release Tab** Release button for Foot Pedal Connection and disconnection.

WARNING: ELECTRIC SHOCK HAZARD. *Determine if the available voltage corresponds to your device. Connecting to the wrong voltage will cause the Vacuum Pump to malfunction or may permanently damage the device!*

The Power Cord must be equipped with a safety plug. Use the enclosed Power Cord for the connection between the power plug and the device socket!

WITHIN THE U.S.A – Use only a listed detachable Power Cord, type SJT, minimum 18AWGx30, 3 conductors, one end configured for NEMA 5-15, other end for IEC320/CEE22!

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

WARNING: EXPLOSION HAZARD. *Do not use the Vacuum Pump in the presence of flammable gases!*

WARNING: ELECTRIC SHOCK HAZARD. *Do not immerse the Vacuum Pump!*

WARNING: *The Vacuum Pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be monitored to verify normal operation in the configuration in which it will be used.*

IMPORTANT NOTE: *Use of cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.*

IMPORTANT NOTE: *The Disposable Vacuum Line and Hydrophobic Filter (K-DVLF-240) has been designed and tested to handle the full vacuum range of the device. Other vacuum lines may not be able to withstand the full vacuum range.*

WARNING: BIOLOGICAL HAZARD. *Always use the disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240). Never use the device if there is any indication that the tubing, the filter or the Vacuum Pump is contaminated.*

If the Vacuum Pump is suspected to be contaminated, do not allow further use of the device and immediately notify your authorised service agent to have the device checked and repaired.

The disposable Vacuum Line with Hydrophobic Filter attached to the Vacuum Pump are for single patient use only and must not be re-used or resterilised. Re-use of this device may result in cross-contamination which may lead to the transmission of infectious diseases. Re-sterilisation of this device may compromise the structural integrity of the device and cause product failure. Once used, this product is considered as infectious and should be disposed of according to local policy for disposal of biohazard waste.

3.5 Supply Voltage Selection

The Vacuum Pump can operate on the voltage range 100 – 240 VAC, 50 – 60 Hz. No fuse selection is required.

If the voltage is changed, it may be necessary to replace the Power Cord to an appropriately rated Power Cord.

Ensure that the correct Power Cord is connected.

3.6 Electromagnetic Compatibility

The Vacuum Pump is designed to provide a reliable controlled source of vacuum. It has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices as specified by IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources could result in performance disruption of the Vacuum Pump. Evidence of disruption may include erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs cease using the Vacuum Pump and contact your Cook authorised service agent.

Refer to the tables in § 8 of this manual for guidance on electromagnetic emissions, electromagnetic immunity, and recommended separation distance between portable and mobile RF communications equipment and the Vacuum Pump.

3.7 Device Placement

The Vacuum Pump should be placed on a level secure surface, away from heaters, coolers, air-conditioning outlets, mists, splashes and exposure to direct sunlight. It must not be placed in the presence of flammable gases.

The ambient temperature should be between +5°C and +35°C for the Vacuum Pump to function correctly. Position the vacuum pump such that quick and easy disconnection of the power supply plug is not impeded.

3.8 Connection to the Foot Pedal

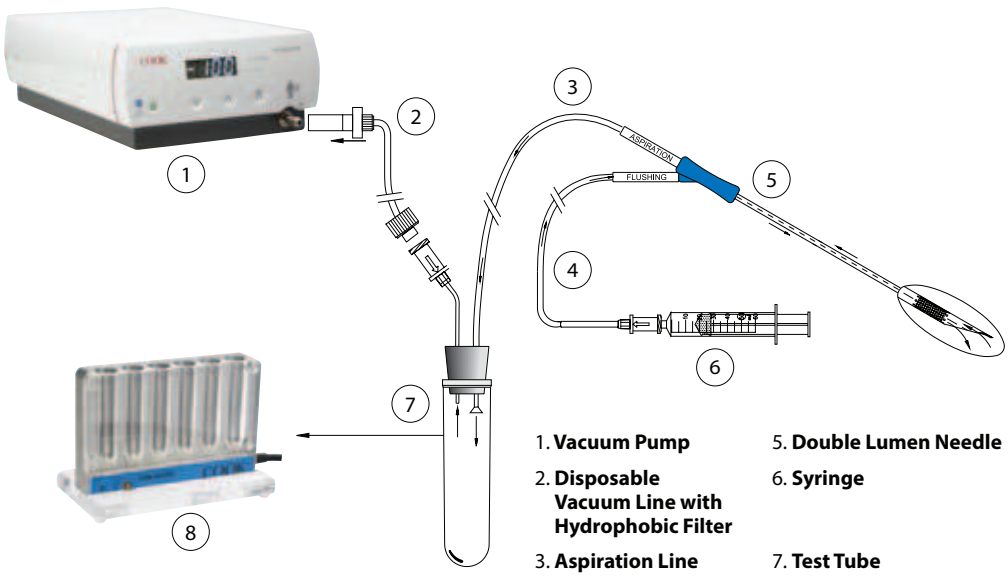
- Connect the Foot Pedal to the Foot Pedal Connection on the rear of the Vacuum Pump.
- The connection must snap into place with an audible click.
- Release the plug by pressing on the sides of the Foot Pedal Connection.

3.9 Vacuum Line and Filter

The Vacuum Pump uses a disposable Vacuum Line with Hydrophobic Filter (re-order code K-DVLF-240).
To prepare and install:

- Connect the silicone tube attached to the filter to the Patient Tube Connection on the Vacuum Pump.
- Connect the luer fitting of the disposable Vacuum Line to the vacuum supply luer fitting of the needle set.
- Connect a Syringe to the Flushing Line of the needle set (if required).

Note: This diagram indicates a Cook K-OPSD needle set.



1. **Vacuum Pump**
2. **Disposable Vacuum Line with Hydrophobic Filter**
3. **Aspiration Line**
4. **Flushing Line**
5. **Double Lumen Needle**
6. **Syringe**
7. **Test Tube**
8. **Test Tube Heater**

The set up is complete and now ready for use.

⚠ ***WARNING: ELECTRIC SHOCK HAZARD.*** *Internal circuitry is energised whenever the Vacuum Pump is connected to mains power irrespective of whether the device is on or in standby.*

3.10 Activating the Device

- Connect the Power Cord to the Power Inlet. The Standby Indicator should light up.
- The Vacuum Pump will either be in the standby mode or active mode depending on the last state the device was in when mains power was disconnected.
- If the Vacuum Pump is in standby, press the Standby Touch-Pad to put the device into an active state.

3.11 Vacuum Setting Adjustment

- Press and hold the appropriate Adjust Vacuum Touch-Pad.
- The vacuum will adjust in 1 mmHg or 0.1 kPa steps depending on the Display Units Setting.
- The selected value appears in the Vacuum Display.
- When the desired vacuum is reached release the Touch-Pad.

3.12 Set Display Units

The measurement units that the Vacuum Pump can display are mmHg and kPa. This setting is indicated by either the mmHg Indicator being lit or the kPa Indicator being lit.

The factory setting is mmHg.

To change this setting:

1. Ensure that the device is in standby mode by using the Standby Touch-Pad.
2. Press ⋀ Adjust Vacuum Touch-Pad Increase once, the Vacuum Display will flash up either:

 Indicates mmHg Mode

 Indicates kPa Mode

3. Press ⋀ Adjust Vacuum Touch-Pad Increase again to toggle between mmHg mode and kPa mode.
4. Once the desired setting is achieved, switch the device into active mode.
5. The appropriate indicator should now be lit up.
6. The device should be displaying in the appropriate units.

3.13 Foot Pedal Function

The Vacuum Pump has two Foot Pedal settings, Latching and Non–Latching.

The factory setting is Non–Latching.

To determine the setting of the device depress the Foot Pedal and observe the behaviour of the device.

3.13.1 Non-Latching Foot Pedal Function

- Press and hold the Foot Pedal.
- The vacuum is applied and a chime sounds every few seconds until the Foot Pedal is released.
- Release the Foot Pedal.
- The vacuum is disconnected and the suction stops.

3.13.2 Latching Foot Pedal Function

- Press and release the Foot Pedal.
- The vacuum is applied and a chime sounds every few seconds.
- Press and release the Foot Pedal.
- The vacuum is disconnected and the suction stops.

IMPORTANT NOTE: *This keystroke must be entered correctly to change the Foot Pedal Function.*

If the Vacuum display does not indicate Latching or Non-Latching Mode, retry the sequence.

3.13.3 Set Foot Pedal Function

To change the setting.

1. Ensure that the Vacuum Pump is in standby mode by using the Standby Touch-Pad.
2. Press the following sequence of Touch-Pads on the front panel to enter set Foot Pedal Function mode where Adjust Vacuum Touch-Pads are ⓐ, ⓥ and Boost Touch-Pad is ⓑ.

ⓐ ⓥ ⓑ ⓑ ⓐ ⓑ ⓥ ⓑ ⓥ

The Vacuum Display should now show either:


Indicates Latching Mode


Indicates Non-Latching Mode

If neither of these are displayed, repeat steps 1 & 2.

3. Press ⓥ Adjust Vacuum Touch-Pad Decrease to toggle between Latching and Non-Latching mode.
4. Switch the device into active mode using the Standby Touch-Pad to exit the procedure.
5. To test that the Foot Pedal Function has been set, depress the Foot Pedal and the device should behave accordingly.

3.14 Boost Touch-Pad

IMPORTANT NOTE: *The boost vacuum may not reach -500mmHg when testing with large gauge needle sets due to lower flow resistance.*

With a disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240), test tube, and needle set attached:

- Activate the Foot Pedal.
- The Vacuum Supplied Indicator lights up.
- Press and hold the Boost Touch-Pad ⓑ, the Boost Indicator lights up.
- The device will reach a maximum vacuum of -500 mmHg (-67.0 kPa). A small overshoot may occur up to -530 mmHg
- Release the Boost Touch-Pad
- The Vacuum Display should reach the pre-selected value within ±5 mmHg.

3.15 Chime Volume Adjustment

1. Ensure that the Vacuum Pump is in standby mode by using the Standby Touch-Pad.
2. The Boost Touch-Pad ⓑ can now be used to adjust the volume.
3. Each touch of the Boost Touch-Pad adjusts the volume in a sequence of 4 steps from minimum volume to maximum volume.

The steps are displayed on the Vacuum Display with each touch of the Boost Touch-Pad.


No Volume


Minimum Volume


Medium Volume


Maximum Volume

4. You can now set the volume to suit your preference.

WARNING: ELECTRIC SHOCK HAZARD. *Internal circuitry is energised whenever the Vacuum Pump is connected to mains power irrespective of whether the device is on or in standby.*

IMPORTANT NOTE: *It is recommended that the Vacuum Pump be given a pre-operation test before each operation.*

IMPORTANT NOTE: *If the vacuum value is not reached or if the value begins to decrease again, then there is a leak. First check the disposable Vacuum Line with Hydrophobic Filter.*

IMPORTANT NOTE: *If you should find or suspect deficiencies in the Vacuum Pump during the described function control, the device must not be used until the authorised service agent has repaired it.*

Never use the Vacuum Pump if there are obvious deficiencies, especially involving the power plugs or the power supply connection cables.

Arrange for repair by an authorised service agent.

3.16 Pre-Operation Test

- Connect the Foot Pedal and the disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240) to the Vacuum Pump.
- Switch the device on.
- Ensure that the device is set to display in mmHg mode (see § 3.12).
- Use the Vacuum Adjust Touch-Pads to select a vacuum between -120 and -170 mmHg.
- Activate the Foot Pedal. The Vacuum Supplied Indicator lights up. The chime sounds.
- The Vacuum Display may momentarily decrease (e.g from -170 to -160 mmHg). The Pump Motor may then be heard to accelerate and bring the vacuum level back to the set level, within ±5 mmHg.
- Close the Vacuum Line by kinking, press and hold the Boost Touch-Pad.
- The device should achieve and display a vacuum of -500 mmHg. Note the vacuum is likely to overshoot and may reach -530 mmHg.
- Release the Boost Touch-Pad and the Vacuum Line.
- Deactivate the Foot Pedal.
- The Vacuum Display should reach the pre-selected value within ±5 mmHg.

The Pre-Operation Test is now successfully completed and the Vacuum Pump is ready for use in the operating room.

4. Installation and Set-up Checklist

Check the following:

- ❑ All items have been supplied.
- ❑ The packaging has been safely stored for future use.
- ❑ All non-sterile items have been removed from plastic covers.
- ❑ The Power Cord is correct for your region.
- ❑ The Vacuum Pump has been placed in a suitable location.
- ❑ The Vacuum Pump has undergone a Pre-Operation Test.
- ❑ The disposable Vacuum Line with Hydrophobic Filter have been connected.
- ❑ The Foot Pedal has been connected.
- ❑ The Vacuum Pump has been activated.
- ❑ The Vacuum Display has been set to the desired units.
- ❑ The vacuum has been adjusted to the desired value.
- ❑ The Foot Pedal Function has been set to the desired setting.

5. Operation of the Device

IMPORTANT NOTE: *To ensure patient safety, the Pre–Operation Test (see §3.16) must be performed prior to each use.*

WARNING: BIOLOGICAL HAZARD. *Always use the disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240). Never use the device if there is any indication that the tubing, the filter or the Vacuum Pump is contaminated.*

If the Vacuum Pump is suspected to be contaminated, do not allow further use of the device and immediately notify your authorised service agent to have the device checked and repaired.

The Disposable Vacuum Line with Hydrophobic Filter attached to the Vacuum Pump are for single patient use only and must not be re-used or resterilised. Re-use of this device may result in cross-contamination which may lead to the transmission of infectious diseases. Re-sterilisation of this device may compromise the structural integrity of the device and cause product failure. Once used, this product is considered as infectious and should be disposed of according to local policy for disposal of biohazard waste.

WARNING: *Always monitor the aspiration vacuum level. An excessive vacuum can lead to damage of the oocyte or other body tissue. See vacuum warning on page 4.*

IMPORTANT NOTE: *Operational Note.*

This section provides general information about the use of the Vacuum Pump. Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The physician must decide on the specific technique and procedure that will accomplish the desired clinical effect.

5.1 Before the Operation

1. Ensure the Vacuum Pump is correctly set up as described in §3 including correct set up of the disposable Vacuum Line with Hydrophobic Filter (see §3.9) and Foot Pedal (see §3.8 & §3.13).
2. Ensure the device has undergone a Pre-Operation Test (see §3.16).
3. Use the Adjust Vacuum Touch-Pads to select the desired vacuum (see §5.3).

5.2 Calibration of Flow Rates

The first step in IVF is to obtain good quality oocytes. Calibrating the correct flow rate is the key to retrieving the maximum number of oocytes in optimal condition. The rate of flow through an aspiration needle and tubing is dependent upon many variables, such as: the differential height between the needle tip and the collection test tube, the inner diameter of the needle, total length of the system and vacuum pressure according to Poiseuille's Law. To ensure an optimal recovery rate with minimal damage to the oocytecumulus complex and zona pellucida, flow rates of 20-25 mL/min are recommended. Calibration can be checked by aspirating water through the aspiration needle and adjusting the vacuum pressure to give the correct flow rate. A flow rate of 20-25 mL/min equates to 24 to 30 seconds to aspirate 10 mL of water.

The vacuum pressure used with a specific gauge and/or type of ovum pick-up needle is at the discretion of the clinician performing the procedure.

5.3 During the Operation

1. Insert the aspiration cannula into the follicle under ultrasound vision.
2. Activate the Foot Pedal to aspirate follicular fluid.
3. Deactivate the Foot Pedal when the follicle is empty.
4. The oocyte and follicular fluid are in the collection receptacle.

5.4 Clearing Blockages in the Aspiration Line/Needle

The vacuum pressure can be boosted to clear blockages in the ovum aspiration needle by activating the boost button on the front panel of the unit.The boost should only be used to clear blockages or obstructions in the aspiration line or aspiration needle when the needle is outside the patient.

5.5 After the Operation

1. Use the Standby Touch-Pad to place the Vacuum Pump in standby mode.
2. Remove the disposable Vacuum Line with Hydrophobic Filter, Power Cord and Foot Pedal.

6. Service and Maintenance

IMPORTANT NOTE: *To guarantee safe operation, it is necessary to carry out proper care and maintenance of the Vacuum Pump and disposables. Regular checks to confirm correct functioning of the device are recommended! New and repaired products must be prepared and tested according to the manual instructions before you use them.*

WARNING: *Do not sterilise the Vacuum Pump!*

WARNING: ELECTRIC SHOCK HAZARD. *Do not immerse the Vacuum Pump!*

IMPORTANT NOTE: *This functionality test must be performed every six months.*

Conversion Note:

mmHg	kPa	mBar
1	*0,13332*	*1,3332*
5	*0,7*	*7*
198	*26,4*	*264*
200	*26,7*	*267*
202	*26,9*	*269*
500	*66,7*	*667*

IMPORTANT NOTE: *If the vacuum value is not reached or if the value begins to decrease again, then there is a leak. Check the disposable Vacuum Line with Hydrophobic Filter.*

WARNING: *If you should find or suspect deficiencies in the Vacuum Pump during the described function control, the device must not be used until it has been repaired by the authorised service agent.*

Never use the Vacuum Pump if there are obvious deficiencies, especially involving the power plugs or the power supply connection cables.

Arrange for repair by an authorised service agent.

To preserve the Vacuum Pump and ensure its proper functioning, proper service, maintenance and storage must be provided for. To protect the patient from infection, all disposables that come into contact with human tissue (eg. test tubes and tubing) must be sterile. Disposables must be discarded after each patient use.

6.1 Cleaning the Device

After each use of the Vacuum Pump, turn off the device and disconnect the device from mains power.

Using an aqueous 70% alcohol (eg. ethanol or isopropyl) solution, moisten a cloth and wipe all external surfaces of the device. Prevent any fluid from entering the device.

Do not use a 100% alcohol solution to clean the device, this may cause damage to the front surface.

6.2 Biannual Functionality Testing

In order to preserve the Vacuum Pump and maintain its safety, regular inspections are necessary for early detection of possible malfunctions.

Regulations stipulate that the user or a qualified technician must regularly test the device to assess its functionality and electrical safety. These tests must be performed on a biannual basis.

6.2.1 Functionality Test

1 **Vacuum Pump under test.**

2 **Manometer compatible 0 to -1000 mBar.**

1. The basic function test is intended to check the Foot Pedal and the vacuum.
2. Ensure that the Vacuum Pump is set to display in mmHg mode (see § 3.12).
3. Connect the Foot Pedal and switch the Vacuum Pump on.
4. Set the vacuum to -200 mmHg.
5. Activate the Foot Pedal Function.
6. The Vacuum Motor and Chime should be audible (refer to §3.15 if no chime) and the Vacuum Supplied Indicator should light up.
7. Deactivate the Foot Pedal Function.
8. Connect a silicone tube and a manometer with vacuum measurement capability to the Patient Tube Connection.
9. Activate the Foot Pedal Function.
10. The manometer should show a vacuum of -267 mBar ±7 mBar.
11. Press and hold the Boost Touch–Pad.
12. The Vacuum Pump should achieve and display a vacuum of -500 ±5 mmHg. Note there may be a small overshoot (up to -530 mmHg). Check the manometer reading corresponds to the Vacuum Pump display ±7 mBar.
13. Release the Boost Touch–Pad.
14. Deactivate the Foot Pedal Function. The basic function test is completed.

If the Vacuum Display is not correct the Vacuum Pump should be serviced by an authorised service agent.

***WARNING:** No user serviceable parts inside!*

6.3 Inspection by an Authorised Service Agent

Inspections at least once a year	For ongoing operational safety of the device, an authorised service agent must maintain the Vacuum Pump annually as per SMA30001. The service agent will assess the operational functionality of the vacuum system.
Authorised service agents	All services such as alterations, repairs, calibrations etc., may only be performed by the manufacturer or by service agents who are authorised by the manufacturer as per SMA30001.
Liability	The manufacturer is free from all liability for the operational safety of the Vacuum Pump if the device has been wilfully opened and unauthorised persons have performed repairs or alterations on it during the warranty period.
Certification	The device owner will receive a signed certificate from the service agent for all inspections or repairs. This certificate states the type and scope of the services rendered, the service date and the name of the service company.
Technical documentation	If the manufacturer provides technical documentation, this does not authorise the user to perform repairs, adjustments or alterations to the Vacuum Pump or disposables.

***WARNING: BIOLOGICAL HAZARD.** The returned product must be clearly marked with a contamination warning and should be sealed in a plastic bag and sealed within a second plastic bag!*

When shipping the Vacuum Pump ensure that any connected disposable Vacuum Line with Hydrophobic Filter is removed prior to transport!

***IMPORTANT NOTE:** When returning goods, use the original packaging. The manufacturer does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging.*

6.4 Return Procedure

All devices or disposables that are returned must be prepared as described below for the protection of the service agent and for safety during transportation.

1. Clean as detailed in §6.1.
2. Seal in a plastic bag and seal within a second plastic bag.
3. Place in the original packaging.
4. Enclose the following information:
   - Owner's name
   - Owner's address
   - Model type
   - Serial number of the equipment (see identification plate)
   - Description of the damage or fault.

The manufacturer has the right to refuse to carry out repairs if the products it receives are contaminated.

7. Disposables

***IMPORTANT NOTE:** For optimal functioning of the Vacuum Pump, use only original disposables.*

The disposable Vacuum Line with Hydrophobic Filter has been designed and tested to handle the full vacuum range of the Vacuum Pump.

Other vacuum lines may not be able to withstand the full vacuum range.

The disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240) is a single use device.

Order No.	Description
K-DVLF-240	Disposable Vacuum Line with Hydrophobic Filter. Consists of a 240 cm low volume aspiration line and a one way hydrophobic filter.

8. Technical Data

Classification according to IEC 60601-1	
Type of protection against electric shock:	Class I equipment
Degree of protection against electric shock:	Type B
Degree of protection against harmful ingress of solids and water:	IP41
Specifications	
Power Supply:	100 - 240 VAC
Frequency:	50 - 60 Hz
Maximum current:	500 mA (115 VAC) 250 mA (240 VAC)
Maximum power consumption:	60 VA
Environmental operating conditions:	+5°C to +35°C 10% to 75% RH 700 hPa to 1060 hPa
Storage and transport directions:	+5°C to +40°C 10% to 75% RH
Manufactured and tested to the following standards:	IEC 60601-1: 1988 + A1: 1991 + A2: 1995 IEC 60601-1: 2005 IEC 60601-1-2: 2007 ISO 10079-1: 1999 VACUUM PUMP WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH: ANSI/AAMI ES60601-1(2005 + C1: 09 + A2: 10), CAN/CSA-C22.2 No. 60601-1(2008), E363262
Performance class:	High Vacuum / Low Flow (ISO 10079-1)
Dimensions:	200 mm wide x 100 mm high x 350 mm deep
Weight:	3.2 kg (7.1 lb)
Vacuum Ranges:	-10 mmHg to -500 mmHg in 1 mmHg increments. -1.0 kPa to -67.0 kPa in 0.1 kPa increments.
Vacuum Range Accuracy:	±5 mmHg (±0.7 kPa)

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions Test	*Compliance*	*Electromagnetic Environment Guidance*
RF emissions CISPR 11	Group 1	The Vacuum Pump 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 Vacuum Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions Test	*Compliance*	*Electromagnetic Environment Guidance*
RF emissions CISPR 11	Group 1	The Vacuum Pump 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 Vacuum Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity Test	*IEC 60601 Test Level*	*Compliance Level*	*Electromagnetic Environment Guidance*
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 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 (EFT) IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines N/A for input/output	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line-to-line ± 2 kV line-to-ground	± 1 kV line-to-line ± 2 kV line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 0.5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (95% dip in U_T) for 5 seconds	0% U_T for 0.5 cycle 0% U_T for 1 cycle 70% U_T (30% dip in U_T) for 25 cycles 0% U_T for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vacuum Pump requires continued operation during power mains interruptions, it is recommended that the Vacuum Pump be powered from an uninterruptible power supply or a battery. Note: Compliance level in accordance with IEC61000-4-11 Ed. 2.0
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 0.15 to 80 MHz	6 V	Portable and mobile RF communications equipment should be used no closer to any part of the Vacuum Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommend separation distance** $d = 0.6 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	**Recommend separation distance** $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz 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, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: 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 Vacuum Pump is used exceeds the applicable RF compliance level above, the Vacuum Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Vacuum Pump.

[b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the Vacuum Pump

The Vacuum Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Vacuum Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Vacuum Pump 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 $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d 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 manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for 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

9. Troubleshooting

IMPORTANT NOTE: *Should any errors persist, contact your COOK distributor.*

Error and Alarm Indicator	**Source of Error**	**Elimination of Error**
Vacuum Pump will not turn on.	Power supply cord is not connected. Mains power switch is not turned on.	Check the power supply connection. (Refer to §3.10).
Displays do not illuminate.	The device is in standby mode.	Check that the Standby Indicator is illuminated orange. Press the Standby Touch-Pad. (Refer to §3.10).
Desired aspiration vacuum is not achieved.	Foot Pedal is defective.	Disconnect the Foot Pedal from the rear of the device without applying pressure to the Foot Pedal and re-connect the Foot Pedal.
	Leak in the Vacuum Line or the Filter is wet.	Change the Vacuum Line and Filter. (Refer to §7).
Chime Volume Adjustment does not adjust.	Power supply cord is not connected. Mains power is not turned on.	Check the power supply connection. (Refer to §3.10).
	The device is not in standby.	The device is functionally active, press the Standby Touch-Pad to place the device in standby. (Refer to §3.15).
Vacuum Pump displays the Vacuum in wrong units.	The Display Units setting is set to either mmHg or kPa.	Set the Display Units setting to desired units, either mmHg or kPa. (Refer to §3.12).
Vacuum stays on when the Foot Pedal is depressed and released.	The Foot Pedal Function is set to Latching.	Set the Foot Pedal Function to Non–Latching. (Refer to §3.13.3).
Vacuum doesn't stay on when Foot Pedal is depressed and released.	The Foot Pedal Function is set to Non–Latching.	Set the Foot Pedal Function to the Latching. (Refer to §3.13.3).
Vacuum Pump displays an error code in the form of ER1 to 5.	Device has an internal fault.	Contact service agent.

10. Limited Warranty

COOK AUSTRALIA warrants to the purchasers of this device that at time of manufacture, the product was prepared and tested in accordance with good manufacturing practices and guidelines specified by the Australian Therapeutic Goods Administration or relevant competent authority.

In the event of product failure under normal use, due to defects in material or workmanship, within a period of one (1) year from the date of purchase, the product will be repaired, or at Cook's option, replaced, at no charge. This limited warranty does not apply to products subjected to abnormal use or conditions, improper storage, damaged by accident, misuse or abuse, improper line voltage or to products altered or serviced by anyone other than Cook Australia or its authorised agent.

The foregoing limited warranty is exclusive and in lieu of all other warranties whether written, oral, expressed or implied. In particular, Cook Australia does not warrant that the product is suitable for the needs of the purchaser and there are no warranties given as to merchantability or fitness for a particular purpose. Cook Australia's representations concerning fitness for purpose or suitability for use by any purchaser does not extend beyond those representations set out in the Cook Australia literature that accompanies the product. Cook Australia assumes that the purchaser is experienced in the use of this device and is able to judge from his/her own expertise the suitability or otherwise of the product for the intended use. Cook Australia conducts a technical advisory service, which can be consulted by a purchaser or intended purchaser on an advisory basis.

After one (1) year from the date of purchase, this device will be repaired for a repair charge equal to the cost of parts, labour and transport.

Before returning a product for any reason, please contact your nearest Cook distributor for assistance and instructions.

Cook Australia reserves the right to change or discontinue this product without notice.

10.1 Liability

Because Cook Australia has no control or influence over the conditions under which this device is used, over its method of use or administration, or on handling of the product after it leaves its possession, Cook Australia takes no responsibility for the results, use and/or performance of the product. Cook Australia expects that use of the product will be confined to trained and expert users.

In no event will Cook Australia be liable for any direct or indirect damages including incidental, consequential or special damages, arising out of or in connection with the use or performance of the product.

If the manufacturer provides you with technical documentation, this does not authorise you to perform repairs, adjustments or alterations on the device or disposables.

No representative of Cook Australia and no vendor or lessor of the product is authorised to change any of the foregoing terms and conditions, and the purchaser accepts the product subject to all terms and conditions herein, subject always to any contrary provisions which are necessarily implied by stature or law notwithstanding the within terms and conditions.

10.2 Life of Product

The expected service life of this product is deemed to be seven (7) years. After this time Cook Australia will no longer be responsible for this product.

11. Index

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