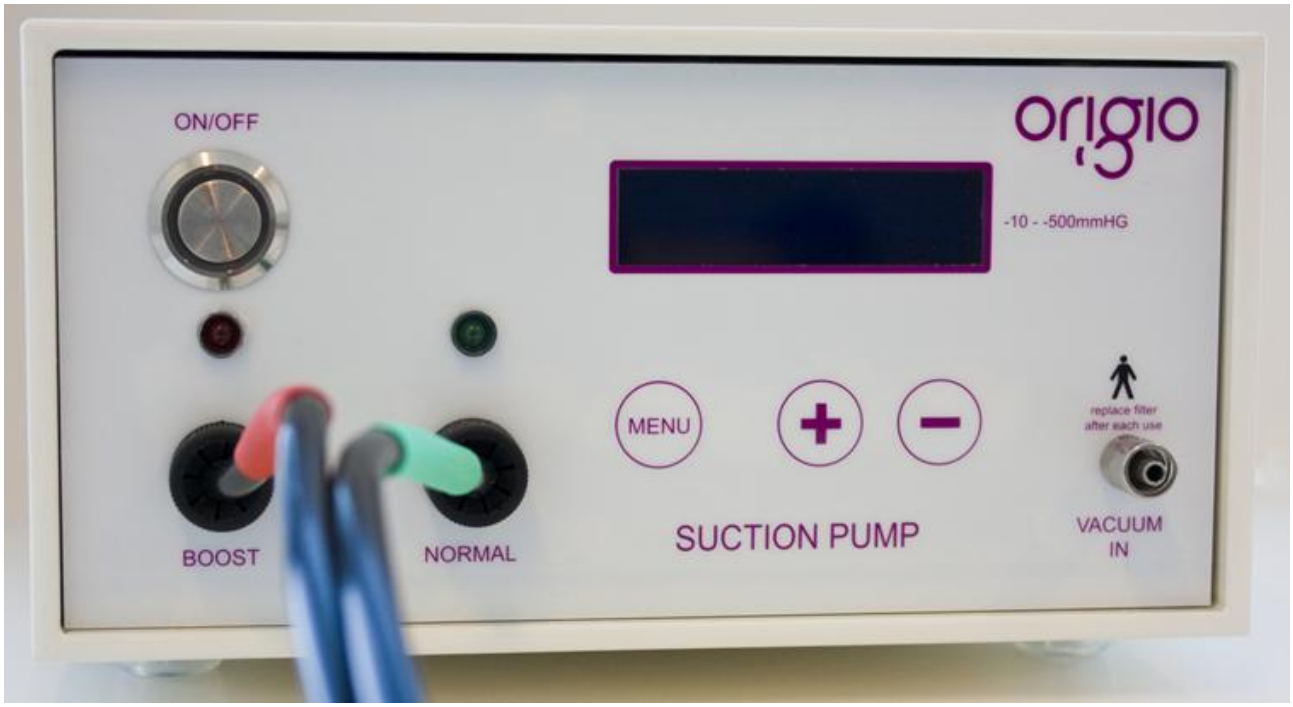
# INSTRUCTIONS FOR USE

## SPUMPV1 Suction Pump




CE
0543

# SPUMPV1 – INSTRUCTIONS FOR USE

**COPYRIGHT**


Document: IFU for SPUMPV1 version 2.

**Service address:**

Please refer to your local ORIGIO a/s distributor for details of your nearest authorized service engineer.

# SPUMPV1 – INSTRUCTIONS FOR USE

**WARNING: READ THIS MANUAL**

Please familiarize 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.

**CAUTION:**

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

Disposal of this product must be undertaken with regard to the WEEE directive.

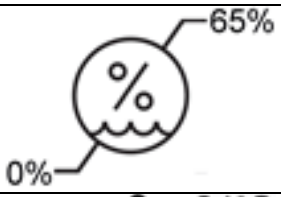
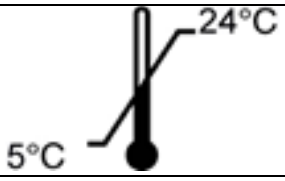
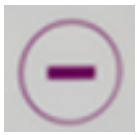
This symbol indicates that this product may not be treated as municipal waste. Please ensure that this product is properly disposed of as inappropriate waste handling of this product may cause potential hazards to the environment and human health. For more detailed information about disposal of this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

# SPUMPV1 – INSTRUCTIONS FOR USE

## CONTENTS

## Explanation of pictograms

The following pictograms appear on the device:

| | | | |
|---|---|---|---|
|  | Before connection, read the manual |  | Humidity limitations |
|  | On/Off |  | Temperature limitations |
|  | Increase Vacuum Set-Point |  | Fragile |
|  | Decrease Vacuum Set-Point |  | This way up |
|  | Menu |  | Keep out of rain |
|  | CE-Marking |  | Class 2 Product |
|  | Dispose of in accordance with WEEE directive (2002/96/EC) |  | Type B Applied part |
|  | Manufacturer |  | SPUMPV1 |
|  | Date of manufacture |  | Serial Number |

## Warnings, Cautions, and Important Notes

Throughout these Instructions for Use, blocks of text may be accompanied by a pictogram and/or printed in bold type. These blocks are WARNINGS, CAUTIONS, 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

**CAUTION**:
These instructions point out special service procedures or precautions that you must follow to avoid damaging the device!

**IMPORTANT NOTE**:
This provides special information that facilitates maintenance or clarifies important instructions. Please pay particular attention to the Safety Instructions *see Chapter 1.*

## Manual Structure

This manual has a table of contents to help you find section titles quickly.
There is a troubleshooting guide in *Chapter 9* to help you to troubleshoot problems.

## 1. Safety Instructions

This manual describes the operation and intended use of the device and the disposables.

It is essential to use this document to familiarize yourself with the functions and the operation of the device 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 device 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 a one-way hydrophobic bacteria filter between the collection receptacle and the device. This should prevent body fluids from penetrating the device.

Never use the device 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 authorized service engineer to have the device checked and repaired.

Always monitor the Suction Pump 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 Suction Pump pressures can lead to the potential for decreased oocyte quality and, consequently, decreased development and fertilization potential. For oocyte aspiration, only use the highest vacuum Suction Pump pressure necessary to achieve the required flow rate for the size aspiration needle being used. The higher vacuum Suction Pump pressures should only be used if required to clear blockages or obstructions in the Suction Pump line or aspiration needle.

The Pre-Operation Test (see *Chapter 3 Paragraph 14*) must be performed prior to each operation. If a device defect is suspected or confirmed, stop using the device until an authorized service engineer has checked it.

Internal circuitry is energized whenever the device is connected to mains power irrespective of whether the device is on. 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 pump housing. Refer servicing to an authorized service engineer.

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

Please refer all servicing to the manufacturer’s authorized service engineer.

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

For safety reasons, only use original disposables see *Chapter 7, Disposables*.

# SPUMPV1 – INSTRUCTIONS FOR USE

**WARNING.**
Please familiarize yourself with the safety instructions before using the device.

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

**CAUTION:**
Replacement device and disposables.

**WARNING:**
Avoid contamination.

**WARNING:**
Monitor the vacuum.

**CAUTION:**
Electric shock hazard.

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

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

**WARNING:**
Use only original disposables.

# 2. About the SPUMPV1 Suction Pump

### 2.1 Intended Use

The SPUMPV1 is a vacuum pump intended for the aspiration of body fluids and cells; in particular oocyte aspiration.

**Guidance for the use and limitations of the equipment:**
The equipment is intended for use within a health care facility only.

**Contraindications**
Not intended for use where ovarian aspiration or the aspiration of ovarian fluid is contraindicated. For short term operation only, not for continuous drainage.

### 2.2 Device Description

The device is designed to maintain a vacuum accurately at a user specified setting with a (normal) range of approximately -10mmHg to -210mmHg. The device will maintain the vacuum within approximately ±5mmHg. The device can also boost the vacuum to approximately -500mmHg from any setting (Boost).

### 2.3 Precautions for Device Use

In the event of any electrical or mechanical fault during use or entry of fluid into the SPUMPV1 Suction Pump, cease use of the device until it has been checked by an authorized service engineer.

## 3. Installation and Set-Up

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

### 3.1 Unpacking

1. SPUMPV1

- User Manual: Instructions for Use
- Quick IFU: Quick Instruction for use
- Installation Manual: Installation Manual
- QC-Certificate

2. SPUMPV1 Device


3. Disposable Hydrophobic Filter

(Bag of 25 pieces)

4. Reusable Suction Pump Adaptors

30114 Tubing connector (6 mm push fit/female type)

30004 Tubing connector (female/female type)

5. Foot Pedal including air tubes


6. Mains supply cord set

(power supply PDM30US12* and mains cord)

**IMPORTANT NOTE:**

**POWER SUPPLY**

* The mains supply cord set used with the equipment must be an approved type acceptable to the authorities in the country where the equipment is sold. The pump is only provided with the mains cord for the EU.

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

Remove all items from packaging materials.

**IMPORTANT NOTE:**
It is important to retain packaging for future use. *(Refer to Chapter 6, Paragraph 4, Return Procedure).*

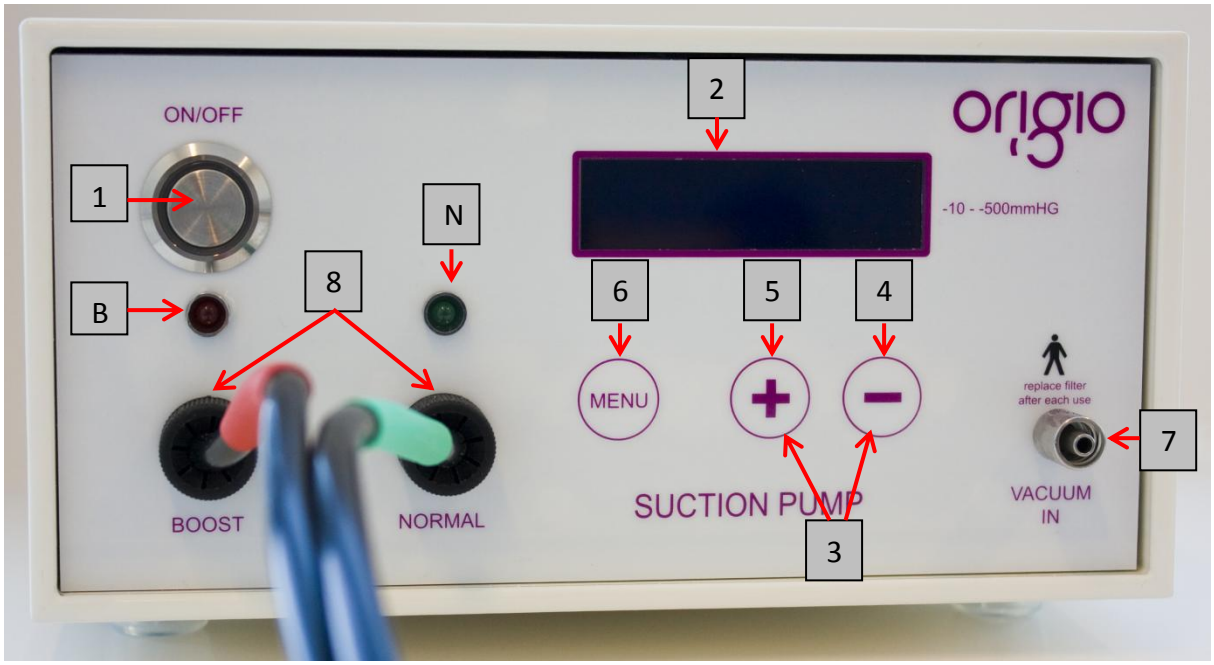
### 3.2 You Need to Supply

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

The following items are not supplied:

- Single/Double Lumen needle
- Aspiration fluid/media
- A source of sterile distilled water
- Test tube heater and test tube
- Vacuum tubing set

### 3.3 Front of the Device




**1** **On/Off Switch**
Indicates the powered on state, Blue = Active. To completely switch off the device unplug the mains cord from the wall socket.

**2** **Vacuum Display**
Displays the measured Vacuum in mm/Hg.

**3** **Vacuum Adjust Indicators**
Indicates Set-Point adjustment.

**4** **Vacuum Adjust Touch-Pad**
Decrease, Press to decrease the vacuum Set-Point.

**5** **Vacuum Adjust Touch-Pad**
Increase, Press to increase the vacuum Set-Point.

**6** **Menu Touch-Pad**
Press to access the menu options.

**7** **Vacuum In - Patient Tube Connection**
Male Luer lock fitting for connection to the hydrophobic filter and follicle aspiration set.
Note: We supply two types of reusable suction pump adaptors which can be used to convert the suction pump system to accept male luer connection tubing sets /Oocyte needle sets (30004) and 6mm push fit tubing line sets with inline filters built in (30114).

**8** **Foot Pedal Connection**
Connect the foot pedal to this point.

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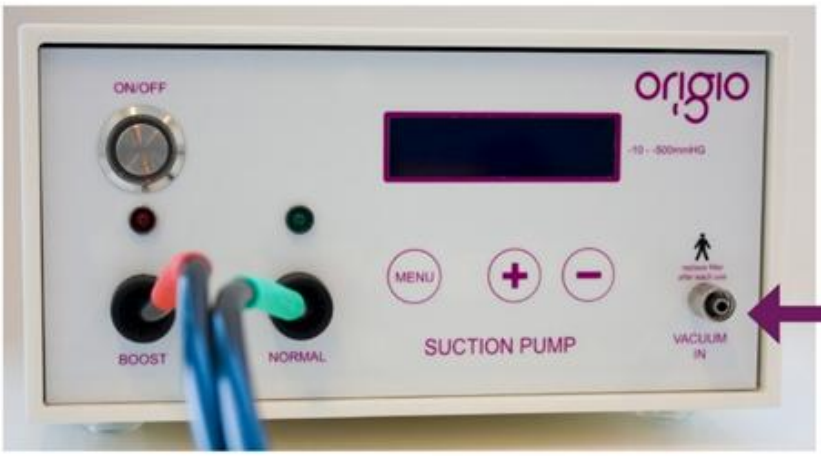
**N** **Normal Vacuum Indicator**
This green LED when lit up indicates when Normal vacuum is in use. (standard operation)

**B** **Boost Vacuum Indicator**
This red LED when lit up indicates when Boost vacuum is in use. (special occasion)

**Connection of hydrophobic filter**
Before each procedure the hydrophobic filter should be replaced. Do not operate the suction pump without this filter; this can damage the pump.


If you are not using the SPUMPV1 suction pump system with ORIGIO Oocyte Follicle Aspiration needle sets then you may require an adaptor which should be connected to the VACUUM IN port on the front panel of the device.




Either: 30004

Or: 30114

### 3.4 Rear of the Device


| | | |
|---|---|---|
| **NO** | **Exhaust opening** | Keep free, do not attach any item to this point. |
| **P** | **Mains Power Inlet** | Connect the mains cord to the power supply (PDM30US12), then connect the power supply to this point.*<br>Then connect the mains cord into the wall socket. |

### 3.5 Supply Voltage Selection

The device can operate on the voltage range 100-240VAC, 47-63Hz. 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 supply (PDM30US12) and mains cord are connected.*

**IMPORTANT NOTE:**

**POWER SUPPLY**

* The mains supply cord set used with the equipment must be an approved type acceptable to the authorities in the country where the equipment is sold.

**WARNING: ELECTRIC SHOCK HAZARD**

Determine if the available voltage corresponds to your device. Connecting to the wrong voltage will cause the device 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!

### 3.6 Electromagnetic Compatibility

The SPUMPV1 Suction Pump has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices as specified by NEN-EN-IEC 60601-1:2006. 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 Suction Pump. Evidence of disruption may include erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs cease using the Suction Pump and contact your ORIGIO a/s authorized service engineer.

### 3.7 Device Placement

The device 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 +24°C for the SPUMPV1 to function correctly.

**WARNING:**

**EXPLOSION HAZARD**
Do not use the device in the presence of flammable gases!

**WARNING:**

**ELECTRIC SHOCK HAZARD**
Do not immerse the device!

### 3.8 Follicle aspiration set, filter and adapter set

The SPUMPV1 uses a Disposable filter. To prepare and install:

- Connect the disposable filter on the suction pump Vacuum-in port.
- Connect the follicle aspiration set to the disposable filter. If the Follicle Aspiration set does not fit try one of the following suction pump adaptors supplied with the device (30004 & 30114) to convert the pump to fit to the tubing set you are going to connect to the pump. The two types of adaptors supplied and the VACUUM IN connection on the front panel of the system should fit most types of the follicle aspiration tubing lines. If in doubt please contact your local ORIGIO representative.
- Connect a syringe to the flushing line (if required).

**Filter and adapter connections**

**RIGHT**

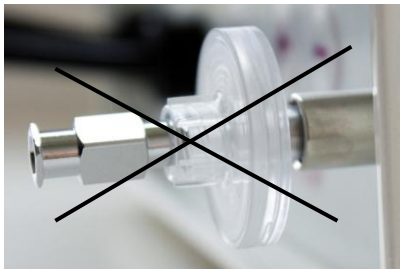
Filter

Female/female adapter and filter

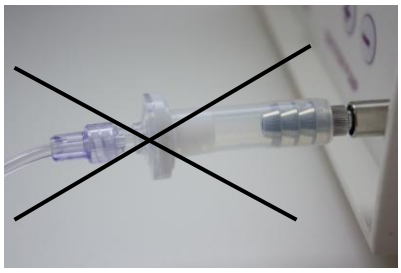
Male/female adapter for tubing line sets with filters built in

**WRONG**

Female/female



Male/female



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**Note: This diagram indicates and ORIGIO a/s Suction Pump including required accessories**

1

3

30114

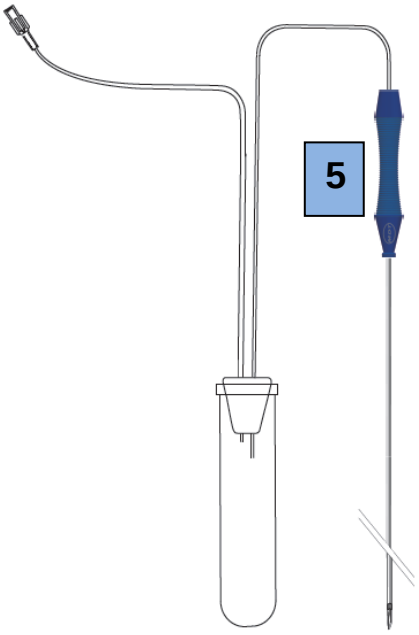
30004

4

2



6



5

1. Power supply and mains cord
2. Suction Pump
3. Adapter. Male/Female or Female/Female. (if required)
4. Disposable filter
5. Follicle aspiration set with single/double lumen needle
6. Color coded pedals

The set up is complete and now ready for use.

**CAUTION:**
The adapters supplied, disposable filter and the Suction Pump Set have 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. For optimal functioning of the device, use ORIGIO disposables. ORIGIO follicle aspiration sets have been designed and tested to handle the full vacuum range of the device. Other follicle aspiration sets or vacuum lines may perform differently when connected to this device. Please test the set up first before clinical use.

Please ensure that when connecting the adapter the thread is correctly aligned to avoid cross threading.
Use finger tight pressure to connect the adapter to the vacuum-in port.
No tools are required.

See Section 7. Disposables

**Set up test:**

- Attach the Follicle aspiration set including vacuum tubing sets and adapters if required to the pump and make sure each connection is tight and without leaks.
- Attach a test tube to the bung and submerge the needle tip in a reservoir filled with water.
- Set the vacuum rate as defined by the user.
- Activate the pump for 30 seconds and determine the contents of the test tube, multiply this by two to obtain the flow per minute. This flow should be at the same level as you normally use.

**WARNING: AVOID CONTAMINATION**
Always use a hydrophobic filter (article code HPFILTER). Never use the device if there is any indication that the tubing, the filter or the device is contaminated.

If the device is suspected to be contaminated, do not allow further use of the device and immediately notify your authorized service engineer to have the device checked.

The follicle aspiration set and filter attached to the suction pump are for single use only with one patient and should not be reused or desterilized. Reusing these articles can result in cross contamination and can lead to infectious diseases. After use these products are classed as infectious waste. All infectious waste must be disposed of in a suitable biohazard container or bag. No sharps shall be placed into biohazard bags. All sharps should be disposed of in suitable puncture proof containers.

### 3.9 Activating the Device

- Connect the power cord to the power inlet. The on/off indicator should light up when pushing it on. Left side, blue light.
- The device will either be in the off mode or active mode depending on the last state the device was in when mains power was disconnected.

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

### 3.10 Vacuum Setting Adjustment

- Press and hold the appropriate adjust vacuum touch-pad.
- The vacuum will adjust in 1 mmHg- and 10 mmHg steps.
- The selected value appears in the vacuum display.
- When the desired vacuum is reached release the touch-pad.

### 3.11 Display Unit

The measurement unit that the device displays is in mmHg.

### 3.12 Foot Pedal Function

The device has two foot pedal settings, normal (green) and boost (red).

#### 3.12.1 Normal Foot Pedal Function

- Press and hold the green foot pedal.
- The vacuum is applied and a tone (beep) sounds when the vacuum is reached.
  **Note**: As long as the footswitch is pressed, this situation will be maintained
- Release the foot pedal - the vacuum is disconnected and the suction stops.

#### 3.12.2 Boost Foot Pedal Function

- Press and hold the red foot pedal.
- The vacuum is applied and a repeatable beeps sound when the vacuum is reached.
- The device will reach the maximum vacuum of –500mmHg.
  **Note**: As long as the footswitch is pressed, this situation will be maintained
- Release the foot pedal – the vacuum is disconnected and the suction stops.

#### 3.12.3 Volume settings

If needed the volume level and duration of the repeatable beeps can be decreased as well as increased.

*Change the volume level:*
Press the “MENU”-pad once.
Adjust the level with the ⊕-pad and ⊖-pad.
You will hear how the beeps will sound.
The volume level can be set between 0 and 40.

*Change the volume duration:*
Press the “MENU”-pad twice.
Adjust the duration with the ⊕-pad and ⊖-pad.
The duration can be set between 0 and 20.

### 3.13 Pre-Operation Test

Before an operation is started a pre-operation test should be performed:

- Check the connection of the foot pedal.
- Connect and check connection of the reusable adaptor if required
- Connect the disposable filter to the device.
- Switch the device on.
- Use the vacuum adjust touch-pads to select the desired vacuum. The chosen value will be shown as the SET value in the display. The ⊕-pad is used to increase the desired vacuum, the ⊖-pad is used to decrease the desired value.
- Activate the green foot pedal (normal). The green vacuum supplied Indicator lights up. The chime sounds when the vacuum has been reached. Release the foot pedal.
- The Vacuum Display should reach the pre-selected value within ±5mmHg.
- Activate the red foot pedal (Boost). The red vacuum supplied Indicator lights up. The chime sounds continuously until the maximum vacuum has been reached (approximately 500mm/Hg). Release the foot pedal.
- The vacuum display should reach the pre-selected value within ±5mmHg.

The pre–operation test is now successfully completed and the device is ready for use in the operating room.

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

**IMPORTANT NOTE**:
It is mandatory that the devise be given a pre-operation test before each operation.

**CAUTION**:
If the value is not reached or if the value begins to decrease again, then there is a leak. First check the follicle aspiration set and filter.

**CAUTION**:
If you should find or suspect deficiencies in the device during the described function control, the device must not be used until the authorized service engineer has repaired it. Never use the device if there are obvious deficiencies, especially involving the power plugs or the power supply connection cables. Only use (PDM30US12) as power supply. Arrange for repair by an authorized service engineer.

## 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 packaging.
- The power cord is correct for your region.
- The device has been placed in a suitable location.
- The device has undergone a pre-operational test.
- The filter and the follicle aspiration set have been connected.
- The device has been activated.
- The vacuum has been adjusted to the desired value.

## 5. Operation of the device

This section provides general information about the use of this device. 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 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 the inner diameter of the needle, total length of the system and vacuum pressure according to Poiseulles' Law.
To ensure an optimal recovery rate with minimal damage to the oocyte cumulus complex and zona pellucida, flow rates of 20-25mL/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.
For 16 and 17 gauge ovum pick-up needles, the most commonly used vacuum pressures range from -110 to -200mmHg to achieve a flow rate of 20-25ml/min. The vacuum pressure used with a specific gauge ovum pick-up needle is at the discretion of the clinician performing the procedure.

#### 5.1.1 Before the Operation

1. Ensure the device is correctly set up as described in Chapter 3 including correct set up of the filter and foot pedal.
   The follicle aspiration set is set up as described in the instructions for use accompanying the products.
2. Ensure the device has undergone a pre-operation test.
3. Use the adjust vacuum touch-pads to select the desired vacuum.

### 5.2 During the Operation

1. Insert the suction pump 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.

### 5.3 After the Operation

**1.** Use the on-off button to switch the device off.
2. Remove the follicle aspiration set and filter, power cord and foot pedal.

**IMPORTANT NOTE**:
To ensure patient safety, the pre-operation test must be performed prior to each use.

**WARNING: AVOID CONTAMINATION**
Always use a one-way hydrophobic filter. Never use the device if there is any indication that the tubing, the filter or the device is contaminated. If the device is suspected to be contaminated, do not allow further use of the device and immediately notify your authorized service engineer to have the device checked and repaired.

**WARNING: MONITOR THE VACUUM**
Always monitor the suction pump vacuum level. An excessive vacuum can lead to damage of the oocyte or other body tissue. See vacuum warning in Chapter 1.

**IMPORTANT NOTE:**
Operational Note.

**WARNING: BIOLOGICAL HAZARD.**
Observe all hygiene regulations when disposing of the follicle aspiration set and filter.

## 6. Service and Maintenance

To preserve the device 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 (e.g. 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 device, turn off the device and disconnect the device from mains power.
Using an aqueous 70% alcohol (e.g. 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 the device.

### 6.2 Biannual Functionally Testing

In order to preserve the device and maintain its safety, regular inspections are necessary for early detection of possible malfunctions. Regulations stipulate that the user or a qualified service engineer must regularly test the device to assess its functionality. The electrical safety test is part of the maintenance program as performed by the qualified service engineer. The functionality test as well as the electrical safety test must be performed on a biannual basis.

#### 6.2.1 Functionality Test



**1** Device under test

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

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1. The basic function test is intended to check the foot pedal and the vacuum.
2. Switch the device on
3. Set the vacuum to -200 mmHg.
4. Activate the foot pedal function.
5. The vacuum motor and chime should be audible and the vacuum supplied indicator should light up.
6. Deactivate the foot pedal
7. Connect a silicone tube and a manometer with vacuum measurement capability to the patient tube connection.
8. Activate the foot pedal function.
9. The manometer should show a vacuum of -267mBar ±7mBar
10. Press and hold the boost touch-pad.
11. The device should achieve and display a vacuum of -500 mmHg ±5mmHg. Note there may be a small overshoot (around -530 mmHg) before the ready state of -500 mmHg is reached.
12. The manometer shows a vacuum of -667 mBar ±7mBar.
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 device should be serviced by an authorized service engineer.

**IMPORTANT NOTE:**
To guarantee safe operation, it is necessary to carry out proper care and maintenance of the device 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.

**CAUTION:**
Do not sterilize the device!

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

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

**Conversion Note:**

| mmHg | mBar |
|---|---|
| 1 | 1.3332 |
| 5 | 7 |
| 198 | 264 |
| 200 | 267 |
| 202 | 269 |
| 500 | 667 |

**CAUTION:**
If the value is not reached or if the value begins to decrease again, then there is a leak. Check the follicle aspiration set and filter.

**CAUTION:**
If you should find or suspect deficiencies in the device during the described function control, the device must not be used until it has been repaired by the authorized service engineer. Never use the device if there are obvious deficiencies, especially involving the power plugs or the power supply connection cables. Only use (PDM30US12) as power supply. Arrange for repair by an authorized service engineer.

### 6.3 Inspection by an authorized service engineer

**Inspections at least once a year**
For ongoing operational safety of the device, an authorized service engineer must maintain the device annually.

**Authorized service engineers**
All services such as alterations, repairs, calibrations etc., may only be performed by the manufacturer or by service engineers who are authorized by the manufacturer.

**Liability**
The manufacturer is free from all liability for the operational safety of the device if the device has been willfully opened and unauthorized persons have performed repairs or alterations on it during the warranty period.

**Certification**
The device owner will receive a signed certificate from the service engineer 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 authorize the user to perform repairs, adjustments or alterations to the device or disposables.

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

### 6.4 Return Procedure

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

1. Clean as detailed in *Chapter 6, Paragraph 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 backside of the device)
   Description of the damage or fault
   RMA Number which can be obtained from ORIGIO a/s only.

The manufacturer has the right to refuse to carry out repairs if the products it receives are contaminated or do not comply with the above return procedure.

**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 SPUMPV1 ensure that any connected follicle aspiration set, the hydrophobic filter, the power cord are 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.

## 7. Disposables

The following items are preferable for use with the suction equipment:

*Hydrophobic filters*

| Order No. | Description |
|---|---|
| HPFILTER | Hydrophobic filter for pump |

*Follicle aspiration sets*

| Order No. | Description |
|---|---|
| **Oocyte RS** | |
| SL1603011 | OocyteRS16G N30-A100-S100 |
| SL1603014 | OocyteRS16G N30-A100-S040 |
| SL1603014L | OocyteRS16G N30-A100-S040L |
| SL1603064 | OocyteRS16G N30-A060-S040 |
| SL1603044 | OocyteRS16G N30-A040-S040 |
| SL1703011 | OocyteRS17G N30-A100-S100 |
| SL1703014 | OocyteRS17G N30-A100-S040 |
| SL1703014L | OocyteRS17G N30-A100-S040L |
| SL1703064 | OocyteRS17G N30-A060-S040 |
| SL1703044 | OocyteRS17G N30-A040-S040 |
| SL1753011 | OocyteRS175G N30-A100-S100 |
| SL1753014 | OocyteRS175G N30-A100-S040 |
| SL1753014L | OocyteRS175G N30-A100-S040L |
| SL1753064 | OocyteRS175G N30-A060-S040 |
| SL1753044 | OocyteRS175G N30-A040-S040 |
| SL1853011 | OocyteRS185G N30-A100-S100 |
| SL1853014 | OocyteRS185G N30-A100-S040 |
| SL1853064 | OocyteRS185G N30-A060-S040 |
| SL1853044 | OocyteRS185G N30-A040-S040 |
| **Oocyte RSS** | |
| SL1703011M | OocyteRSS17G N30-A100-S100M |
| SL1753011N | OocyteRSS175G N30-A100-S100N |
| SL1753014N | OocyteRSS175G N30-A100-S040N |
| SL1753011B | OocyteRSS175G N30-A100-S100B |
| SL1753014B | OocyteRSS175G N30-A100-S040B |
| **Oocyte RD** | |
| DL16035111 | OocyteRD16G N35-A100-S100-F100 |
| DL16035141 | OocyteRD16G N35-A100-S040-F100 |
| DL16035641 | OocyteRD16G N35-A060-S040-F100 |

*Reusable Adaptors*

The following items may be required for use with the suction equipment:

| Order No. | Description |
|---|---|
| 30114 | Tubing connector (Male/Female) |
| 30004 | Tubing connector (Female/Female) |
| VTS200MM | Vacuum Tube 200 cm male connectors |
| VTS200FF | Vacuum Tube 200 cm female connectors |
| VTS200MF | Vacuum Tube 200 cm male/female connectors |

**IMPORTANT NOTE:**
For optimal functioning of the device, use only original disposables. The follicle aspiration sets have been designed and tested to handle the full vacuum range of the device. Other follicle aspiration sets or vacuum lines may not be able to withstand the full vacuum range.

**IMPORTANT NOTE:**
Inspect suction tubing and any other components that are subject to wear or damage for any visual defects, do not use when damaged.

## 8. Technical Data

**Classification according to IEC 60601-1**

| | |
|---|---|
| Type of protection against electric shock: | Class 2 equipment |
| Degree of protection against electric shock: | Type B |
| Degree of protection against harmful ingress of solids and water: | IP41 |
| Mode of operation | Continuous operation |

**Specifications**

| | |
|---|---|
| Power supply: | PDM30US12*<br>Input 100-240VAC / 0.6-0.4A<br>Output 12VDC / 2.5A |
| Environmental conditions: | +5°C to +24°C and a relative humidity of max. 65% |
| Storage and transport directions: | +5°C to +35°C and a relative humidity of max. 65%<br>Store in a cool dry place |
| Manufactured and tested to the following standards: | IEC 60601-1 standards<br>IEC 60601-1-2<br>EN 60601-1<br>ISO 10079-1 |
| Performance class: | High Vacuum / Low Flow (ISO 10079-1) |
| Dimensions: | 200 mm wide x<br>115 mm high x<br>250 mm deep |
| Weight: | 4.6kg |
| Vacuum Ranges: | -10mmHg to -210mmHg in 1mmHg increments (normal)<br>-500mmHg (Max Boost) |
| Vacuum Range Accuracy | ±5mmHg |

**IMPORTANT NOTE:**
Should any errors persist, contact your ORIGIO a/s distributor.

**IMPORTANT NOTE:**

**POWERSUPPLY**
* The main supply cord set used with the equipment must be an approved type acceptable to the authorities in the country where the equipment is sold.

### 8.1 Technical Guidance Data

Guidance and Manufacturer's Declaration/el. Magn. Emission
Table 201
Med. Device acc. To group 1/class B, tested acc. To CISPR 11

| The SPUMPV1 is suitable for use in the specified electromagnetic environment. The customer and/or the user of the equipment should assure that it is used in an electromagnetic environment as described below. | | |
|---|---|---|
| **Emission Test** | **Compliance** | **Electromagnetic environment Guidance** |
| RF emission/CISPR 11 | Group 1 | The SPUMPV1 uses RF energy only for internal function.<br>Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emission/CISPR 11 | Conducted<br>Class B | The equipment is suitable for use in all establishments directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| | Radiated<br>Class B | The equipment is suitable for use in all establishments, including domestic establishments. |
| Harmonic emissions<br>EN 61000-3-2 | Not applicable | No test because of power consumption smaller than Standard limit (23 VA; 9 VA) |
| Flicker emissions<br>EN 61000-3-3 | | |

Guidance and Manufacturer's Declaration/el. Magn. Immunity
Table 202. See sub clauses 6.8.201 a) 3.)

The SPUMPV1 is suitable for use in the specified electromagnetic environment. The customer and/or the user of the equipment should assure that it is used in an electromagnetic environment as described below.

| **Immunity Test** | **Test-Level** | **Compliance-Level** | **Electromagnetic environment Guidance** |
|---|---|---|---|
| Electrostatic discharge (ESD)<br>EN 61000-4-2 | +/- 6 KV Contact-<br>+/- 8 KV Air-Discharge | +/- 6 KV Contact-<br>+/- 8 KV Air-Discharge | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30 %. |
| Radiated RF EN 61000-4-3 | 0,08-1 GHz:<br>5V/m<br>1-3 GHz:<br>10V/m | 3 V/m<br>80 MHz-<br>3 GHz | Field strength from fixed RF transmitters, as determined by an el. magn. site survey, should be less than the compliance level in each frequency range |
| Electrical fast transient<br>EN 61000-4-4 | +/- 2 KV<br>+/- 1 KV | +/- 2 KV | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>EN 61000-4-5 | +/- 2 KV<br>L,N-PE:<br>+/- 2 KV<br>L/N:<br>+/- 1 KV | +/- 2 KV<br>L,N-PE:<br>+/- 2 KV<br>L/N:<br>+/- 1 KV | |
| Conducted disturbances<br>EN 61000-4-6 | 3 V<br>150 KHz-80MHz | 3 V | RF communication equipment should be used no closer to SPUMPV1, including cables than the separation distance d calculated from the following equation: $d = 1,2\sqrt{P}$ |
| Power frequency magnetic field<br>(50Hz/60Hz)<br>EN 61000-4-8 | 3 A/m | 3 A/m | |
| Voltage dips, short interruptions on power supply input lines<br>EN 61000-411 | <5% U/<br>10 msec<br>70% U/<br>0,5 sec.<br>40% U/<br>0,1 sec<br>5% U/<br>5 sec. | <5% U/<br>10 msec (B)<br>70% U/<br>0,5 sec. (B)<br>40% U/<br>0,1 sec (B)<br>5% U/<br>5 sec. | If the user of the device requires continued operation during power mains interruption, it is recommended to power the device from a battery or USV. |

# SPUMPV1 – INSTRUCTIONS FOR USE

Recommended Separation Distances between Portable and Mobile RF Communication Equipment and the SPUMPV1

For equipment that are not life supporting

Table 206 after EN60601-12/Tab. 206

The SPUMPV1 is suitable for use in a specified, field strength-controlled, electromagnetic environment. The customer and/or the user of the equipment can help avoiding electromagnetical disturbances by keeping the following separation distances, depending from the power of the transmitter:

| | Separation distance (depending on transmitter frequency) [m] | | |
|---|---|---|---|
| Output power rating of the transmitter ($P_{Sender}$) [W] | 150 kHz-80 MHz $d = 1{,}2 \times \sqrt{P_{Sender}}$ metres | 80 MHz-800 MHz $d = 1{,}2 \times \sqrt{P_{Sender}}$ metres | 800 MHz-2,5 GHz $d = 2{,}3 \times \sqrt{P_{Sender}}$ metres |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 2 | 1,7 | 1,7 | 3,25 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |

Field strength from fixed RF transmitters, as determined by an el. magn. 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

## 9. Troubleshooting

Below are useable solutions when you encounter any problems with you device, please ensure to read this list before contacting a service representative.

**What do I do when the power light does not light up?**

- Check whether the power cord is connected properly to the device.
  If not, connect the power cord properly.
- Check if there is power in the wall socket.
  If not, contact your electrician.

**What do I do when the vacuum does not work?**

- Check whether the foot pedals are connected properly to the device.
  If not, then connect the foot pedals properly.
- Check whether the power cord is connected properly to the device.
  If not, connect the power cord properly.
- Check if there is power in the wall socket.
  If not, contact your electrician.
- Check whether the filter is wet.
  When wet, then replace the filter.
- Check whether the adaptor it fitted firmly to the pump.
  Gently finger tighten pump adaptor to vacuum-in port
  **Note**: No tools are required.

**What do I do when the red light does not come on when the Boost is in use?**

- Check whether the foot pedals are connected properly to the device.
  If not, then connect the foot pedals properly.
- Check whether the power cord is connected properly to the device.
  If not, connect the power cord properly.
- Check if there is power in the wall socket.
  If not, contact your electrician.
  When all is checked then call an authorized service representative to change the red light.

**What do I do when the green light does not come on when the Normal vacuum is in use?**

- Check whether the foot pedals are connected properly to the device.
  If not, then connect the foot pedals properly.
- Check whether the power cord is connected properly to the device.
  If not, connect the power cord properly.
- Check if there is power in the wall socket.
  If not, contact your electrician.
  When all is checked then call an authorized service representative to change the green light.

**What do I do when the ACT value does not reach the SET value?**

- Check whether the follicle aspiration set is properly connected to the disposable filter.
  If not, then connect the follicle aspiration set properly to the disposable filter.
  The general deviation may be approximately 5mm/Hg.

## 10. Limited Warranty

ORIGIO a/s 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. 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 option of ORIGIO a/s, 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 ORIGIO a/s or its authorized engineer. The foregoing limited warranty is exclusive and in lieu of all other warranties whether written, oral, expressed or implied. In particular, ORIGIO a/s 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. ORIGIO a/s representations concerning fitness for purpose or suitability for use by any purchaser do not extend beyond those representations set out in the ORIGIO a/s literature that accompanies the product. ORIGIO a/s 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. ORIGIO a/s 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, labor and transport. Before returning a product for any reason, please contact your nearest ORIGIO a/s distributor for assistance and instructions. ORIGIO a/s reserves the right to change or discontinue this product without notice.

### 10.1 Liability

Because ORIGIO a/s 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, ORIGIO a/s takes no responsibility for the results, use and/or performance of the product. ORIGIO a/s expects that use of the product will be confined to trained and expert users. In no event will ORIGIO a/s 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 authorize you to perform repairs, adjustments or alterations on the device or disposables.
No representative of ORIGIO a/s and no vendor or lessor of the product is authorized 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 life of this product is deemed to be five years. After this time ORIGIO a/s will no longer be responsible for this product.

**Manufacturer**

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