EN DeVilbiss® Vacu-Aide® QSU Suction Unit Instruction Guide 7314 Series

RX ONLY

Made in U.S.A.

ES Guía de Instrucciones para la Unidad de Succión de la Serie 7314 de DeVilbiss® Vacu-Aide® QSU

RX ÚNICAMENTE

Hecho en EE.UU.

FR Manuel utilisateur de l'apirateur de mucosités Vacu-Aide® QSU Série 7314

UNIQUEMENT SUR PRESCRIPTION

Fabriqué aux U.S.A.

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SYMBOL DEFINITIONS

⚠	Attention, consult instruction guide	- —◉— +	Center positive polarity indicator		Battery charging
	Consult instructions for use		Type BF equipment-applied part		Low battery
	Date of manufacture		"On" compressor		Keep dry
⎓	Direct current		"Off" compressor (external battery charging)		Do not get wet
~	Alternating current		External power	℞ ONLY	Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
0-3	Choking Hazard – Small parts not for children under 3 years or any individuals who have a tendency to place inedible object in their mouths.				
IP12	Protected against solid foreign objects of ≥ 50 mm AND vertically falling water drops when enclosure is tilted up to 15°				
	This device contains electrical and/or electronic equipment that must be recycled per EU Directive 2012/19/EU- Waste Electrical and Electronic Equipment (WEEE)				

IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, basic safety precautions should always be followed. Read all instructions before using. Important information is highlighted by these terms:

DANGER– Urgent safety information for hazards that will cause serious injury or death.

WARNING– Important safety information for hazards that might cause serious injury.

CAUTION– Information for preventing damage to the product.

NOTE– Information to which you should pay special attention.

READ ALL INSTRUCTIONS BEFORE USING THIS DEVICE.

SAVE THESE INSTRUCTIONS.

DANGER

To reduce the risk of electrocution:

1. Do not use while bathing.
2. Do not place or store product where it can fall or be pulled into a tub or sink.
3. Do not place in or drop into water or other liquid.
4. Do not reach for a product that has fallen into water. Unplug immediately.

WARNING

To reduce the risk of burns, electrocution, fire or injury to persons:

1. Close supervision is necessary when this product is used by, on, or near children or physically incapacitated individuals.
2. Use this product only for its intended use as described in this guide.
3. Keep the power cord away from heated surfaces.
4. Never use while drowsy or asleep.
5. Do not cover the unit or the AC to DC adapter while power is applied.
6. Never operate this product if
   a. It has a damaged power cord or plug.
   b. It is not working properly.
   c. It has been dropped or damaged.
   d. It has been dropped into water.

   Instead return the product to an authorized DeVilbiss Healthcare service center for examination and repair.

INTERNATIONAL TRAVEL

The 7314 series is equipped with an AC to DC adapter allowing operation on any AC voltage (100-240 VAC, 50/60 Hz). However the correct power cord must be used to connect to adaptable wall power.

NOTE– *Check power cord for adaptability before using.*

INTRODUCTION

Your DeVilbiss suction unit is a compact medical suctioning device which has been designed for reliable, portable operation. Following the recommended operating and maintenance procedures outlined in this instruction guide will maximize the life of this product.

Intended Use Statement

The device is to be used to remove fluids from the airway or respiratory support system and infectious materials from wounds. The device creates a negative pressure (vacuum) that draws fluids through disposable tubing that is connected to a collection container. The fluids are trapped in the collection container for proper disposal. It is for use on the order of a physician only.

Contraindications

The Vacu-Aide QSU should not be used for:

- thoracic drainage
- nasogastric suction

DANGER

The DeVilbiss Vacu-Aide is a vacuum suction device designed for the collection of nonflammable fluid materials in medical applications only. Improper use during medical applications can cause injury or death. For all medical applications:

1. All suctioning should be done in strict accordance with appropriate procedures that have been established by a licensed medical authority.
2. Some attachments or accessories may not fit the tubing supplied. All attachments or accessories should be checked prior to use to assure proper fit.

ACCESSORY/REPLACEMENT ITEMS

The following items can be purchased separately as accessories or replacement items for your 7314 Series DeVilbiss Suction Unit:

Description	Part No.	Description	Part No.
6’ patient tubing	6305D-611	Splash Guard (12 pack) for Disposable Container with internal filter cartridge	7305D-641
800 Disposable Container (container and lid only) for use with external bacteria filter (48 pack)	7305D-602	Carrying case	7314D-606
Collection Container Kit (800 ml disposable container, external bacteria filter, elbow, 3 3/8” and 6’tubing package)	7305D-603	12V DC power cord (1 each)	7304D-619
Collection Container Kit (Internal filter cartridge, splash guard, 800 ml container, 4/” and 6’ tubing package)	7305D-633	AC to DC adapter/charger (see Specifications for manufacturer information)	7314P-613
800 ml disposable container with internal filter cartridge, splash guard and 4/” tubing (48 each)	7305D-632	Power cord for US	DV51D-606
Filter cartridge (12 pack) (For Disposable Container with internal filter)	7305D-635	Power cord for Continental Europe	DV51D-607
Collection Container Kit (1200 ml reusable container, external bacteria filter, elbow, 4/” tubing)	7314D-603	Power cord for UK	DV51D-608
1200 ml reusable container (external bacteria filter, elbow, 4/” tubing) (6 pack)	7314D-604	Power cord for Australia	DV51D-609
External bacteria filter (non-sterile) (12 pack) For reusable container and disposable container with external filter	7305D-608	Power cord for Japan	DV51D-613

NOTE– *The use of electrical cables and accessories other than those specified in this manual or referenced documents may result in increased electromagnetic emissions from the product or decreased electromagnetic immunity of the product.*

IMPORTANT PARTS

7314 Series DeVilbiss Vacu-Aide QSU Suction Unit

with Disposable Container and Internal Filter Cartridge

1. Vacuum gauge
2. Vacuum regulator knob
3. 6' patient tubing
4. Patient tubing connector
5. Disposable container with lid (float shut off incorporated into lid) and filter cartridge
6. Filter cartridge with 4/" tubing
7. DC power input (on side)
8. Power switch
9. LED power lights

AC to DC adapter (not shown)

DC power cord (not shown) optional

Internal rechargeable battery (not shown) 7314P series only

Carrying case (not shown) 7314P series only

with Disposable Container and External Bacteria Filter

1. Vacuum gauge
2. Vacuum regulator knob
3. 3/" connection tubing
4. 6' patient tubing
5. Patient tubing connector
6. Disposable container with lid (float shut off incorporated into lid)
7. DC power input (on side)
8. Power switch
9. LED power lights
10. External bacteria filter

AC to DC adapter (not shown)

DC power cord (not shown) optional

Internal rechargeable battery (not shown) 7314P series only

Carrying case (not shown) 7314P series only

with Reusable Container and External Bacteria Filter

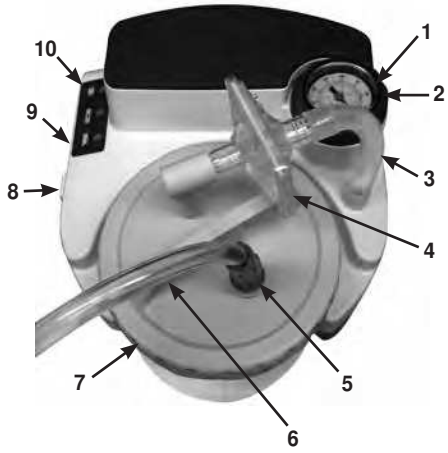
1. Vacuum gauge
2. Vacuum regulator knob
3. 4/" connection tubing
4. External bacteria filter
5. Patient tubing connector
6. 6' patient tubing
7. Lid
8. DC power input (on side)
9. Power switch
10. LED power lights

AC to DC adapter (not shown)

DC power cord (not shown) optional

Internal rechargeable battery (not shown) 7314P series only

Carrying case (not shown) 7314P series only



Disposable Container with Internal Filter Cartridge and Splash Guard

1. 4/" connection tubing
2. Filter cartridge **(Do not get wet)**
3. Lid
4. Jar
5. Splash guard
6. Patient tubing connector

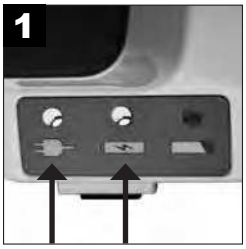
Disposable Container with External Bacteria Filter

1. 3/" connection tubing
2. Patient tubing connector
3. Lid
4. Jar
5. Connection elbow
6. Bacteria filter

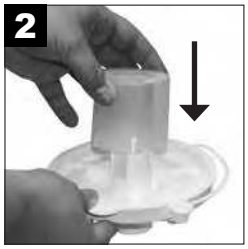
Reusable Container with External Bacteria Filter

1. 4/" connection tubing
2. Lid with o-ring
3. Overflow valve
4. Jar
5. Patient tubing connector
6. Connection elbow
7. Bacteria filter

SET-UP & OPERATION



Fully charge battery for **17 HOURS**. (7314P series only)

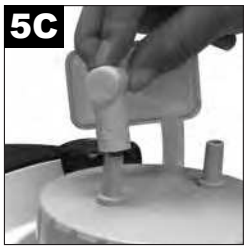


If applicable, ensure splash guard is securely attached to inside of lid over filter cartridge.

Securely attach lid to container.

Insert container into holder and gently push into place.
NOTE – *Do not use excessive force. Pushing container down too hard could cause potential leak or loss of suction.*

Disposable Container w/ internal filter cartridge Connection: Attach 4/" tubing from filter cartridge to tubing connector on unit.



Reusable Container and Disposable Container w/external Bacteria Filter Connection: Connect either end of the 4-3/8" (reusable) or 3-3/8" (disposable) tubing to the tubing connector then connect the other end to the bacteria filter. Ensure that the clear side of the bacteria filter is toward elbow and bottle when installing. Do not reverse direction of filter. The bacteria filter should then be connected to the 90˚ elbow connection, and the elbow should be connected to the top of the container lid where it says <Vacuum>.

Attach 6' patient tubing to container lid at outlet labeled <Patient>.

Ensure power switch is ⏻ "off".

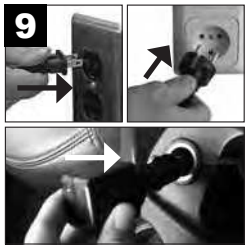
NOTE–*Inspect suction tubing and container for leaks, cracks, etc. and assure that all connections are secure and without leaks before using.*

7314P - Select desired power source. (Skip steps 8 if using internal battery power.)

7314D series (non-battery label)

NOTE– *The 7314D series is not factory equipped with an internal rechargeable battery. 7314P series is factory equipped with an internal rechargeable battery and all information regarding battery operation in this guide is applicable.*

If using AC or DC power, plug the small connector into the DC power input on the side of unit.



Plug the other end into an AC wall outlet or DC receptacle.
NOTE– *The AC adapter may become warm to the touch during charging or running of the unit. This is normal.*

Turn the unit ⏻ "on".

Adjust the suction level.

Verify suction level.
NOTE - *Always verify suction level before beginning by occluding open end of patient tubing while observing gauge. Adjust knob to desired level.*

WARNING

If the unit is not receiving power from an external source or the battery was not recharged, the low battery indicator light will remain on and the performance of the unit will drop off rapidly. Switch to another power source immediately after the low battery light appears to avoid an interrupted suction procedure.

NOTE– *Gauge is for reference only. If the unit sustains a severe drop, accuracy of the gauge must be checked.*

CAUTION– *When automatic float shut-off is activated, contents of the collection container should be emptied. Further suctioning could cause damage to the vacuum pump.*

CAUTION– *Should fluid be aspirated back into the unit, equipment provider servicing is necessary as possible vacuum pump damage may result.*

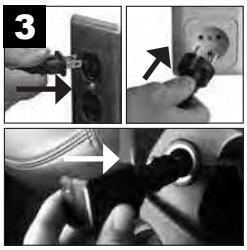
BATTERY CHARGING & FILTER MAINTENANCE

Battery Charging (7314P Series Only)

On 7314P series, the units are equipped with a factory-installed rechargeable battery. The unit will have a light for low battery and charge indication.

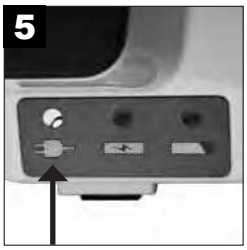
Ensure power switch is ⏻ "off".

Plug the small connector of the AC or DC adapter into the DC power input.



Plug the other end into an AC wall outlet or DC receptacle.

Battery charging begins; 17 hours for full charge.



Battery charging complete.

LED Explanations:

Green– Illuminated when external power is supplied to unit from an AC or DC power source.	**Yellow**– Battery is being charged. Light will go out when battery is fully charged.	**Red**– Low battery. Seek another power source and charge battery as soon as possible when light illuminates.

NOTE – *Charge battery for a minimum of 17 hours before first use.*

NOTE – *Fully recharge battery after each use. The unit will continue to float charge the battery after the charge indicator turns off, so leave the unit connected to AC when not in use.*

CAUTION– *Discharging the battery completely will shorten the life of the battery. Do not operate the unit more than a few minutes if the low battery indicator light is lit. Recharge as soon as possible.*

NOTE – *Unit run time will decrease as the battery ages.*

NOTE – *Unit run time will also be reduced by letting the battery sit at a discharged state for extended periods.*

STORAGE NOTE - *Battery should be charged for a minimum of 17 hours prior to storage, and at least once every 6 months. Important - If battery recharge is delayed beyond 6 months, battery may be able to provide full run time after completion of 3 full charge and discharge cycles.*

NOTE– *A fully charged battery will provide approximately 60 minutes of continuous operation at a zero vacuum level (free flow). Operation time will decrease with higher vacuum levels.*

NOTE– *When charging the battery, use an external power source and verify that the charge light illuminates when the unit is in the "Off" position. If the battery does not charge, please be sure the model you are using has a battery installed prior to contacting your authorized DeVilbiss Healthcare provider.*

NOTE– *The internal rechargeable battery is sealed lead-acid. Contact your local authorities for instruction on proper disposal.*

NOTE– *Do not connect the AC adapter to an outlet controlled by a switch to ensure power is supplied to unit at all times.*

NOTE– *Do not connect the DC power cord to an outlet that is not constantly energized.*

Changing Internal Filter Cartridge (single-patient use) Disposable Container

Change filter cartridge if overflow occurs or every two months, whichever comes first.

Turn unit ⏻ "off".

Remove filter cartridge and 4/" tubing.

Install new cartridge and attach tubing.

NOTE– *Do not substitute any other material for this filter cartridge. Substitution may lead to contamination or poor performance; use only DeVilbiss filter cartridges.*

NOTE– *The filter cartridge contains a hydrophobic filter. If the filter media becomes wet, air flow will be stopped. The filter cartridge must then be replaced. Do not remove filter media from filter cartridge.*

NOTE– *Filter cartridges are included with each disposable container. They are also available separately (7305D-635 12/pack).*

Changing External Bacteria Filter (single-patient use) Reusable Container and/or Disposable Containter

Change bacteria filter if overflow occurs or every two months, whichever comes first.

Turn unit ⏻ "off".

Remove filter by disconnecting it from suction unit and lid assembly.

Replace with a clean DeVilbiss bacteria filter (non-sterile) and remount to suction unit and lid. Ensure that the clear side of the bacteria filter is toward elbow and bottle when installing. Do not reverse direction of filter. Additional filters (7305D-608 12/pack) may be purchased from your authorized DeVilbiss Healthcare provider.

NOTE– *Do not substitute any other material for this bacteria filter. Substitution may lead to contamination or poor performance; use only DeVilbiss filters.*

NOTE– *Bacteria filter must be changed between patients.*

CLEANING INSTRUCTIONS

WARNING

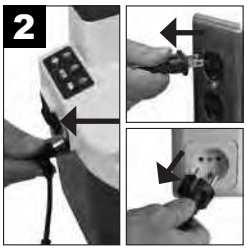
To prevent possible risk of infection from contaminated cleaning/disinfection solutions, always prepare fresh solution for each cleaning cycle and discard solution after each use.

NOTE– *Disinfection information is based on AARC Clinical Practice Guideline Suctioning of the Patient in the Home.*

Disposable Collection Container (with Internal Filter Cartridge)

NOTE– *The disposable collection container and lid are meant for single-patient use.*

Turn unit ⏻ "off" and allow vacuum to drop.



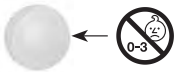
Disconnect from power source.

Disconnect tubing and remove container from holder.

Carefully remove lid and empty contents. **NOTE**– *Container should be emptied and cleaned after each use.*

Remove filter cartridge and 4/" tubing and set aside.

WARNING- ***Do not remove float ball from lid. If removed, float ball may pose a choking hazard.***



Filter MUST NOT get wet. The filter material cannot be removed from the elbow.

Wash container, lid and splash guard in warm water/ dishwashing solution. Rinse with clean, warm water.

Soak in 1 part vinegar (>=5% acetic acid concentration) to 3 parts water (131˚F-149ºF/55˚C-65˚C) solution for 60 minutes. Rinse with clean, warm water and air dry.

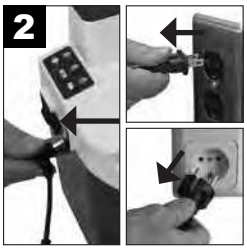
NOTE– *The disassembled container may also be washed in a dishwasher, top shelf only, using a cycle with a water temperature between 131ºF-149ºF/55ºC-65ºC.*

Disposable Collection Container (with External Bacteria Filter)

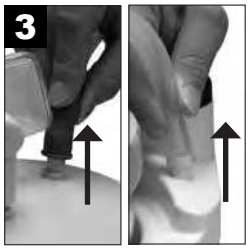
NOTE– *The disposable collection container and lid are meant for single-patient use.*

NOTE– *The disassembled container may also be washed in a dishwasher, top shelf only, using a cycle with a water temperature between 131ºF-149ºF/55ºC-65ºC.*

Turn unit ⏻ "off" and allow vacuum to drop.



Disconnect from power source.



Disconnect tubing and remove container from holder.

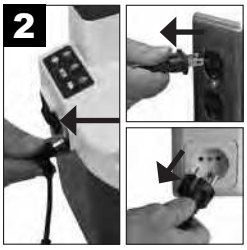
Carefully remove lid and empty contents. **NOTE**– *Container should be emptied and cleaned after each use.*

Remove bacteria filter, elbow, and 3/" tubing and set aside.

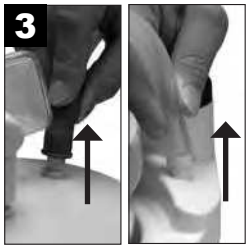
Wash container and lid in warm water/dishwashing solution. Rinse with clean, warm water.

Reusable Collection Container (with External Bacteria Filter)

Turn unit ⏻ "off" and allow vacuum to drop.



Disconnect from power source.



Disconnect tubing and remove container from holder.

Carefully remove lid and empty contents. **NOTE**– *Container should be emptied and cleaned after each use.*

Remove bacteria filter, elbow, and 4/" tubing and set aside.

Wash jar, lid, o-ring, and overflow valve in a solution of warm water with a mild, liquid detergent (e.g. Dawn or Palmolive) and rinse with clean, warm tap water. Then disinfect using one of the following methods.

For single patient use:

1. Soak in 1 part vinegar (>=5% acetic acid concentration) to 3 parts water (131ºF-149ºF/55ºC-65ºC) solution for 60 minutes. Rinse with clean, warm water and air dry in a clean environment.
2. Soak with a commercial (bacterial-germicidal) disinfectant. Follow disinfectant manufacturer's recommended dilution rates and instructions carefully.

For multi patient use:

1. After parts are completely dry, place jar and lid in autoclave with the open end down. Ensure parts are not touching. Run one sterilization steam cycle at 250°F (121°C) for 15 minutes. **NOTE**-J*ar is guaranteed up to 30 cycles of autoclave sterilization at the indicated conditions.*
2. Dispose of and replace filter, tubing and elbow between patients.

6' Patient Tubing (single-patient use)

Disconnect from lid.

Rinse thoroughly by running warm tap water through it.

Follow by soaking in a solution of 1 part vinegar (>=5% acetic acid concentration) to 3 parts water (131ºF-149ºF/55ºC-65ºC) for 60 minutes.Rinse with clean, warm water and air dry.

Keep outer surface clean by wiping with clean, damp cloth .

AC to DC Adapter

Disconnect AC to DC adapter from unit and from power source.

Wipe AC to DC adapter housing and cords with a dry cloth.

Suction Unit (single-patient use)

CAUTION– *Do not submerge in water as this will result in damage to the vacuum pump.*

NOTE–*Do not use any cleaners or disinfectants that contain ammonia, benzene and/or acetone to clean the unit.*

Turn unit ⏻ "off" and allow vacuum to drop.

Disconnect from power source.

Wipe the housing with a clean cloth and any commercial (bacterial-germicidal) disinfectant.

Carrying Case (single-patient use)

Wipe with clean cloth dampened with detergent or disinfectant.

Suction Unit (multi-patient use)

Device Cleaning and Disinfection When There is a Patient Change

When medical devices have already been used with a patient, contamination with human pathogenic germs should be assumed (unless there is evidence to the contrary), and the next patient, user or third party should be protected by appropriate handling and preparation. Therefore, when there is a patient change, people must be protected during the transport and handling of the device and the device must be fully processed, i.e., cleaned and disinfected, by suitably trained personnel before reuse to protect the next patient. The complete processing may only be done by the manufacturer or by a qualified DeVilbiss provider/service technician.

NOTE – *When the unit is used as per instructions under normal conditions the interior of the unit is protected from exposure to pathogens by the in-line filter on the collection container, hence no disinfection of internal components is necessary.*

NOTE – *If the unit is used without an in-line filter then the interior of the unit has been exposed to pathogens and the unit cannot be disinfected.*

NOTE – *If the following processing of the unit by a qualified DeVilbiss provider/technician is not possible, the unit must not be used by another patient!*

DeVilbiss Healthcare recommends that at least the following procedures be carried out by the manufacturer or a qualified third party between uses by different patients.

1. Dispose of all accessory components that are not suitable for reuse, i.e., collection container, filter, tubing and carrying case.
2. With the power switch in the "Off" position, disconnect the DeVilbiss Suction Unit from all external power sources.
3. Visually inspect unit for any damage, missing parts, etc.
4. Wipe the housing with a clean cloth and a commercial (bacterial-germicidal) disinfectant that meets the requirements listed in the NOTE below and is used as per the disinfectant manufacturer's recommended dilution rates and instructions.

CAUTION – *Do not submerge in water as this will result in damage to the vacuum pump.*

NOTE – *Do not use any cleaners or disinfectants that contain ammonia, benzene and/or acetone to clean the unit.*

TROUBLESHOOTING

DANGER

Electric shock hazard. Do not attempt to open or remove cabinet, there are no user-serviceable internal components. If service is required, return unit to a qualified DeVilbiss Healthcare provider or an authorized service center. Opening or tampering with the unit will void warranty.

NOTE– *Your DeVilbiss Suction Unit contains no user-serviceable parts. If you believe your unit is not working properly, BEFORE YOU RETURN IT TO YOUR DEVILBISS HEALTHCARE PROVIDER WHERE YOU PURCHASED IT, PLEASE TAKE A FEW MOMENTS TO CHECK FOR THESE POSSIBLE CAUSES:*

PROBLEM	ACTION
Unit does not turn on when external power is connected. Green external power light does not illuminate.	1. Check power sources and connections. 2. Ensure wall outlet is live by plugging in a lamp.
Pump runs, but there is no suction.	1. Check that all tubing is connected properly. 2. Check tubing connections for breaks or leaks. 3. Ensure that float shut-off in collection container is not activated or filter cartridge occluded. 4. Check for leaks or cracks in collection container assembly.
Low suction.	1. Use vacuum regulator knob to increase suction level. 2. Check system for leaks.
Unit does not turn on (no external power is connected). 7314P Series Only	1. Check that battery is fully charged and/or charge battery.
Battery will not charge (external power and charge indicator lights should be illuminated during charge mode) 7314P Series Only	1. Verify that both external power and charge indicator lights illuminate. 2. Check power sources and connections. 3. Ensure wall outlet is live by plugging in a lamp.

PROVIDER'S NOTES

No routine calibration or service is required provided the device is used in accordance with the manufacturer's directions. In case of a change of patient, the device must be reconditioned to protect the user. Reconditioning must only be carried out by the manufacturer or service provider. Between patients:

1. Visually inspect unit for any damage, missing parts etc.
2. Ensure that unit and accessories are clean.
3. Use an independent vacuum gauge to verify the unit provides the proper vacuum level as stated in Specifications.
4. Discard and replace collection container, filter, and tubing between patients.
5. Wipe the surface using a clean cloth dampened with disinfectant.

SPECIFICATIONS/CLASSIFICATIONS

Size (including container)	8.3 H x 8.0 W x 8.5 D (21.1 cm x 20.3 cm x 21.6 cm) (not including AC to DC adapter)
Weight (including container)	7314P Series - 6.6 lb. (3 kg) (not including AC to DC adapter) 7314D Series - 4.3 lb. (2.0 kg)
Typical Operating Sound Level	55 dBA
Electrical Requirements	100-240V~, 50/60Hz, 1.2A max -—◉—+; 12V ⎓; 33 W Max
Vacuum Range	50-550 mm Hg +/- 10%*
Air Flow @ Pump Inlet:	27 LPM (free flow) typical (may be less when running from internal battery)*
Disposable Collection Container Capacity	800 ml (cc) with 2 filter options
Reusable Collection Container Capacity	1200 ml (cc)
Warranty	Two-years limited, excluding internal battery (7314P series only) and collection container
Internal Battery (7314P Series Only)	90-day
Approvals	IEC 60101-1-2; CSA-C22.2 # 601.1; UL 60601-1; EN 60601-1-2; ISO 10079-1; IEC 60601-1; IEC 60529 IP12; IEC 60601-1-6; CENELEC EN 60601-1
Adapter Manufacturer Information	Emerson Model # AD5012N2LM or Autec Power Systems Model # DTM36-12 or SL Power/Ault Model # MENB1040A1240N02
Environmental Conditions	
Operating Temperature Range	32°F (0°c) - 104°F (40°c)
Operating Relative Humidity	0-95%
Operating Atmospheric Pressure	10.2 psi (70 kPa) - 15.4 psi (106 kPa)
Storage & Transport Temperature Range	-40°F (-40°c) - 158°F (70°c)
Storage & Transport Relative Humidity	0-95%
Storage & Transport Atmospheric Pressure	7.3 psi (50 kPa) - 15.4 psi (106 kPa)
Equipment Classifications	
With respect to protection from electric shock	Class II and internally powered
Degree of protection against electric shock	Type BF Applied Parts
Degree of protection against ingress of liquids	IP12 and ordinary power supply
Mode of Operation	Intermittent Operation: 30 minutes on, 30 minutes off
Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.	
ISO Classification	
7314P series only - Electrically powered medical suction equipment for field and transport use according to EN ISO 10079-1 : 2009	
High Flow/High Vacuum	
7314D series only - Electrically powered medical suction equipment for non-transport use according to EN ISO 10079-1 : 2009	

* Conditions may vary based on altitude above sea level, barometric pressure, and temperature.

Manufacturer's Note

Thank you for choosing a DeVilbiss Suction Unit. We want you to be a satisfied customer. If you have any questions or comments, please send them to our address on the back cover.

For Service Call Your Authorized DeVilbiss Healthcare Provider:

Phone	Purchase Date	Serial #

DEVILBISS GUIDANCE AND MANUFACTURER'S DECLARATION

WARNING

Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

NOTE– *The EMC tables and other guidelines provide information to the customer or user that is essential in determining the suitability of the Equipment or System for the Electromagnetic Environment of use, and in managing the Electromagnetic Environment of use to permit the Equipment or System to perform its intended use without disturbing other Equipment and Systems or non-medical electrical equipment.*

Guidance and Manufacturer's Declaration – Emissions All Equipment and Systems

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

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical Fast Transient/ burst IEC 61000-4-4	±2kV on AC Mains	±2kV on AC Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	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	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be separated from the device by no less than the recommended separation distances calculated/listed below: $D=(1.2)\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	$D=(1.2)\sqrt{P}$ 80 to 800 MHz $D=(2.3)\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum power rating in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (3 Vrms and 3V/m). Interference may occur in the vicinity of equipment containing a transmitter.

For transmitters rated at a maximum output power not listed above, the recommended separation distance D in meters (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.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and this device. This device and system are NOT Life-Supporting

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

Maximum Output Power (Watts)	**Recommended Separation Distances for the device (meters)**		
	150 kHz to 80 MHz $D=(1.2)\sqrt{P}$	80 to 800MHz $D=(1.2)\sqrt{P}$	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 meters (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.