DeVilbiss® Suction Unit Instruction Guide 7305 Series

CAUTION—USA Federal law restricts this device to sale by, or on the order of a physician.

Made in U.S.A.
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IEC SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚠️</td>
<td>Attention, consult instruction guide</td>
</tr>
<tr>
<td>⚡</td>
<td>Center positive polarity indicator</td>
</tr>
<tr>
<td>☔️</td>
<td>Keep dry</td>
</tr>
<tr>
<td>📖</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>⚡</td>
<td>Type BF equipment-applied part</td>
</tr>
<tr>
<td>⚠️</td>
<td>Do not get wet</td>
</tr>
<tr>
<td>⚡</td>
<td>“On” compressor</td>
</tr>
<tr>
<td>⚠️</td>
<td>Choking Hazard – Small parts not for children under 3 years or any individuals who have a tendency to place inedible object in their mouths.</td>
</tr>
<tr>
<td>IPX2</td>
<td>IPX2 vertically falling drops shall have no harmful effects when the enclosure is tilted at an angle up to 15° on either side of the vertical.</td>
</tr>
<tr>
<td>📪</td>
<td>This device contains electrical and/or electronic equipment that must be recycled per EC Directive 2002/96/EC-Waste Electrical &amp; Electronic Equipment</td>
</tr>
</tbody>
</table>

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. 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.

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

4. Keep the power cord away from heated surfaces.
5. Never use while drowsy or asleep.

NOTE - The 7305D series is not factory equipped with an internal rechargeable battery; it may be purchased separately and installed by your DeVilbiss Healthcare provider. 7305P series is factory equipped with an internal rechargeable battery and all information regarding battery operation in this guide is applicable.

DANGER
The DeVilbiss Suction Unit 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.

INTERNATIONAL TRAVEL
The 7305 series is equipped with a switch mode power supply 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. Because of the small size, light weight and DC operation, the DeVilbiss Suction Unit is ideal for providing suction in the home, in transport with optional DC cord, or if your model has an internal rechargeable battery, the unit can be operated anywhere. Two container options give the choice between the standard disposable container or an optional long-term reusable container. Following the recommended operating and maintenance procedures outlined in this instruction guide will maximize the life of this product.

Contraindications
The DeVilbiss Suction Unit should not be used for:
- thoracic drainage
- nasogastric suction

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 bottle. The fluids are trapped in the collection bottle for proper disposal. It is for use on the order of a physician only.

IMPORTANT PARTS

7305 Series DeVilbiss Suction Unit
1. 4¼” connection tubing
2. Vacuum gauge
3. Vacuum regulator knob
4. DC power input (on side)
5. Power switch
6. Collection container
7. Lid
8. Patient tubing
9. Filter cartridge
10. Connection elbow
11. Bacteria filter
AC to DC Adapter (not shown)
DC power cord (not shown) optional
Internal rechargeable battery (not shown) 7305P series only
Carrying case (not shown) 7305P series only

Disposable Collection Container
1. 4¼” connection tubing
2. Filter cartridge (Do not get wet.)
3. Lid
4. Jar
5. Patient tubing connector

Optional Reusable Collection Container
1. 4¼” connection tubing
2. Patient tubing connector
3. Lid w/o-ring
4. Jar
5. Overflow valve
6. Connection elbow
7. Bacteria filter
ACCESSORY/REPLACEMENT ITEMS

The following items can be purchased separately as accessories or replacement items for your 7305 Series DeVilbiss Suction Unit:

<table>
<thead>
<tr>
<th>Description</th>
<th>Part No.</th>
<th>Description</th>
<th>Part No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>6' Patient Tubing</td>
<td>6305D-611</td>
<td>Carrying case</td>
<td>7305D-606</td>
</tr>
<tr>
<td>Collection Container Kit (800 ml disposable container, filter cartridge, 4½” and 6' tubing package)</td>
<td>7305D-633</td>
<td>AC to DC adapter/charger</td>
<td>7305P-613</td>
</tr>
<tr>
<td>800 ml disposable container with filter cartridge and 4½” tubing (48 each)</td>
<td>7305D-632</td>
<td>12V DC power cord (1 each)</td>
<td>7304D-619</td>
</tr>
<tr>
<td>Filter cartridge (12 pack) (For Disposable Container)</td>
<td>7305D-635</td>
<td>Hospital grade power cord (120 VAC)</td>
<td>099HD-614</td>
</tr>
<tr>
<td>Collection Container Kit (1200 ml reusable container, bacteria filter, elbow, 4½” tubing)</td>
<td>7314D-603</td>
<td>Power cord for US</td>
<td>6710D-609</td>
</tr>
<tr>
<td>1200 ml reusable container (bacteria filter, elbow, 4½” tubing) (6 pack)</td>
<td>7314D-604</td>
<td>Power cord for Continental Europe</td>
<td>7305P-631</td>
</tr>
<tr>
<td>Bacteria filter (non-sterile) (12 pack) (For Reusable Container)</td>
<td>7305D-608</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SET-UP

1. Insert container into holder.
2. Attach 4½” tubing from filter cartridge to tubing connector.
3. The patient tubing should be connected to the container lid at the outlet labeled <Patient>.
4. Please assure that all connections are secure and without leaks before using.
5. Verify that unit is at desired suction level before beginning patient suction.

Setup w/Optional Reusable Container

1. Insert container into holder.
2. Connect either end of the 4½” 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 container when installing/re-installing. Do not reverse direction of filter.
3. The bacteria filter should then be connected to the 90˚ elbow connection, and the 90˚ connection should be connected to the top of the container lid where it says <Vacuum>.
4. The patient tubing should be connected to the container lid at the outlet labeled <Patient>.
5. Please assure that all connections are secure and without leaks before using.
6. Verify that unit is at desired suction level before beginning patient suction.

HOW TO OPERATE YOUR 7305 SERIES DEVILBISS SUCTION UNIT

Before connecting the unit to the AC adapter or 12V DC cord, make sure that the power switch located on the side of the unit is in the “Off” position. Select power source desired.

LED Explanations:

L1- Green– External power supplied to unit from AC power source or DC cord. Illuminated when external power is supplied.
L2 - Yellow– Battery is being charged. Light will go out when battery is fully charged. (7305P Series only)
L3 - Red– Low battery. Seek another power source and charge battery as soon as possible when light remains on continuous. (7305P Series only)

AC OPERATION– Plug the small connector of the AC adapter into the DC power input located on the side of the unit. Plug the AC end into a grounded wall-outlet power source.

NOTE– The power supply may become warm to the touch during charging or running of the unit. This is normal.

12V DC OPERATION– (such as a car lighter receptacle). Plug the small connector of the DC power cord into the DC power input on the side of the unit. Plug the large connector into the 12V DC power receptacle of the automobile.

BATTERY OPERATION– Verify that your unit has an internal rechargeable battery; factory installed on models 7305P series or provider installed on models 7305D series (installed as an option). To ensure proper operation from internal battery, fully charge the battery for 10-17 hours as explained in the Battery Charging section. To operate the unit from an internal rechargeable battery, ensure that no external power sources are plugged into the DC power input on the side of the unit.

Turn the unit “On” using the power switch located on the side of the unit. The power indicator light displayed on the top of the unit will indicate which power source is being used by staying continuously lit when external power is connected.

WARNING

If the unit is not receiving power from an external source or the battery was not recharged immediately, 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.

Adjust the vacuum level from 80 to 550 mm Hg by turning the vacuum regulator knob located on the side of the unit (clockwise to increase vacuum and counter-clockwise to decrease vacuum). The gauge located on the top of the unit near the handle will allow you to select a specific level of vacuum. To accurately read the gauge, block the patient end of the hose or cap off the collection bottle and allow the gauge to reach a stable vacuum reading.

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

Suction at the patient is automatically obstructed when liquid level reaches the float shut-off located on the underside of the container lid.

NOTE– Always transport unit with vacuum regulator knob rotated fully clockwise in case unit is dropped.

CAUTION– When automatic float shut-off is activated, contents of the 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

On 7305P series, the units are equipped with a factory-installed rechargeable battery. The unit will have a light for low battery and charge indication. On 7305D series, the units are not factory equipped with a rechargeable battery; check with your equipment provider to determine if your unit has been upgraded with a rechargeable battery.

When you connect the unit to an AC or DC power source using the AC adapter or DC power cord, the green external power light will illuminate. The yellow charge indicator will illuminate while the battery is charging. Verify that this illuminates when charging begins. As the charge nears a full charge, the yellow LED may flash on and off for several minutes. This is normal.

NOTE– A discharged battery will require 10-17 hours (depending on depth of discharge) of charging to reach a full capacity.
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.
NOTE– A fully charged battery on the 7305P series will provide approximately 60 minutes of continuous operation at a zero vacuum level (free flow). Operation time will decrease with higher vacuum levels.
NOTE– If unit is not in use for extended periods, battery should be recharged every 6 months minimum.

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– 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 batteries used in 7305 units are typied as sealed lead-acid. Contact your local authorities for instruction on proper disposal.

CLEANING INSTRUCTIONS

Preparation
1. Shut off unit using power switch and allow vacuum to drop. Disconnect power source from the DC input receptacle on the unit.
2. Disconnect tubing and remove container from holder.
3. Carefully remove lid and empty contents.

NOTE– Container should be emptied and cleaned after each use.

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.

Disposable Collection Container
The disposable collection container and lid are meant for single-patient use.

1. Remove filter cartridge and 4-3/8” tubing and set aside.

NOTE– Filter MUST NOT get wet. The filter material cannot be removed from the elbow (figure A).

WARNING
Do not remove float ball from lid. If removed, float ball may pose a choking hazard (figure B).

2. Wash container and lid in warm water/dishwashing solution. Rinse with clean, warm water.
3. Soak in 1 part vinegar (>=5% acetic acid concentration) to 3 parts water (131°F-149°F/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 131°F-149°F/55°C-65°C.

Optional Reusable Collection Container
1. Remove bacteria filter, 4-3/8” tubing, and connection elbow and set aside. Remove o-ring and overflow valve from lid.
2. 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.
3. For single patient use: After washing, disinfect using one of the following methods:
   a. Soak in 1 part vinegar (>=5% acetic acid concentration) to 3 parts water (131°F-149°F/55°C-65°C) solution for 60 minutes. Rinse with clean, warm water and air dry in a clean environment.
   b. Wash with rubbing alcohol and air dry in a clean environment.
   c. Wash with a commercial (bacterial-germicidal) disinfectant. Follow disinfectant manufacturer’s recommended dilution rates and instructions carefully.
4. For multi-patient use: After washing:
   a. 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– Jar is guaranteed up to 30 cycles of autoclave sterilization at the indicated conditions.
   b. Dispose of and replace filter, tubing and elbow between patients.

Suction Unit:
1. With the power switch in the “Off” position, disconnect the DeVilbiss Suction Unit from all external power sources.
2. Wipe the housing with a clean cloth and any commercial (bacterial-germicidal) disinfectant.

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

Tubing:
1. Disconnect the tubing from the unit.
2. Rinse thoroughly by running warm tap water through it.
3. Follow by soaking in a solution of 1 part vinegar (>=5% acetic acid concentration) to 3 parts water (131°F-149°F/55°C-65°C) for 60 minutes. Rinse with clean, warm water and air dry.
4. Keep the outer surface of the tubing clean by wiping with a clean, damp cloth.
Carrying Case:
1. Wipe the case using a clean cloth dampened with detergent and/or disinfectant.

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

MAINTENANCE
Inspect suction tubing and container for leaks, cracks, etc. before each use.

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.

Changing Filter Cartridge (Disposable Container):
1. Change filter cartridge if overflow occurs or every two months, whichever comes first.
2. Turn unit "off".
3. Remove filter cartridge and 4½" tubing.
4. Install new cartridge and 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, airflow 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 Bacteria Filter (Reusable Container):
1. Change bacteria filter if overflow occurs or every two months, whichever comes first.
2. Remove filter by disconnecting it from suction unit and lid assembly.
3. 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 container when installing/re-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.

TROUBLESHOOTING
NOTE – Your DeVilbiss Suction Unit contains no user-serviceable parts. If you believe your unit is not working properly, BEFORE YOU RETURN IT TO THE HOME MEDICAL EQUIPMENT PROVIDER WHERE YOU PURCHASED IT, please take a few moments to check for these possible causes:

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>ACTION</th>
</tr>
</thead>
</table>
| Unit does not turn on, but green external power light is illuminated. | 1. Check power sources and connections.  
2. Ensure wall outlet is live by plugging in a lamp.  
3. If running from an internal battery, ensure that your unit has a battery installed.  
4. If battery is installed, check that it is fully charged. |
| Pump runs, but there is no vacuum. | 1. Check that all tubing is connected properly.  
2. Check tubing connections for breaks or leaks.  
3. Ensure that float shut-off is not activated.  
4. Check for leaks or cracks in container assembly. |
| Low vacuum. | 1. Use vacuum adjustment knob to increase vacuum level.  
2. Check system for leaks.  
3. Push vacuum adjustment knob in toward unit and then release. |
| Battery will not charge but charge light is illuminated. | 1. Ensure that unit is equipped with an internal battery by contacting your DeVilbiss equipment provider.  
2. Verify that charge light turns on.  
3. Check electrical connections during charging.  
4. 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.

SPECIFICATIONS/CLASSIFICATIONS

<table>
<thead>
<tr>
<th>Size</th>
<th>H x W x D inches (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7305P &amp; 7305D Series</td>
<td>9.0 x 7.0 x 8.0 (22.9 x 17.8 x 20.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight</th>
<th>lb. (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7305D Series</td>
<td>3.8 (1.7)</td>
</tr>
<tr>
<td>7305P Series</td>
<td>6.3 (2.9)</td>
</tr>
</tbody>
</table>

| Electrical Requirements | 100-240 V AC 50/60 Hz .75 A max; 12 V DC, 33 W max |
Internal Rechargeable Battery

7305P Series  Factory Equipped
7305D Series  Not Factory Equipped (provider-installed option)

Vacuum Range

7305P & 7305D Series  80 to 550 mm Hg
Air Flow @ pump inlet: 27 LPM (free flow) typical (may be less when running from internal battery)

Container Capacity

7305 D & P Series  800 ml (cc) Disposable
7305 D & P Series - Optional  1200 ml (cc) Reusable

Environmental Conditions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temperature Range</td>
<td>32°F (0°C) - 104°F (40°C)</td>
</tr>
<tr>
<td>Operating Relative Humidity</td>
<td>0-95%</td>
</tr>
<tr>
<td>Operating Atmospheric Pressure</td>
<td>10.2 psi (70 kPa) - 15.4 psi (106 kPa)</td>
</tr>
<tr>
<td>Storage &amp; Transport Temperature Range</td>
<td>-40°F (-40°C) - 158°F (70°C)</td>
</tr>
<tr>
<td>Storage &amp; Transport Relative Humidity</td>
<td>0-95%</td>
</tr>
<tr>
<td>Storage &amp; Transport Atmospheric Pressure</td>
<td>7.3 psi (50 kPa) - 15.4 psi (106 kPa)</td>
</tr>
</tbody>
</table>

Warranty

7305P Series  Two-years limited, excluding internal battery and container
7305D Series  Two-years limited, excluding container
Internal Battery  90-day

Approvals

7305D & 7305P Series  IEC 601-1; CAN/CSA-C22.2 No. 601.1-M90; UL 60601-1, EN 60601-1-2
7305P meets RTCA/D-160D - section 21 Category M For battery operation only Airline use

Equipment Classifications

With respect to protection from electric shock  Class I and internally powered
Degree of protection against electric shock  Type BF Applied Parts
Degree of protection against ingress of liquids  IPX2 and ordinary power supply
Mode of Operation  Intermittent Operation: 30 minutes on, 30 minutes off

ISO Classification

7305P Series only - Electrically powered medical suction equipment for field and transport use according to ISO 10079-1 : 1999
High Flow/High Vacuum
7305D Series - Electrically powered medical suction equipment for non-transport use according to ISO 10079-1 : 1999

DeVilbiss will make available on request circuit diagrams, parts lists, etc.

TWO-YEAR LIMITED WARRANTY

The compressor portion of the DeVilbiss Suction Unit 7305P & 7305D Series (excluding internal rechargeable batteries) is warranted to be free from defective workmanship and materials for a period of two years from date of purchase. Internal rechargeable batteries are warranted for 90 days. Any defective part(s) will be repaired or replaced at DeVilbiss Healthcare’s option if the unit has not been tampered with or used improperly during that period. Make certain that any malfunction is not due to inadequate cleaning or failure to follow the instructions. If repair is necessary, contact your DeVilbiss Healthcare Provider or DeVilbiss Service Department for instructions: U.S.A. 800-338-1988 or 814-443-4881, Europe +49-621-178-98-230.

NOTE—This warranty does not cover providing a loaner unit, compensating for costs incurred in rental while said unit is under repair, or costs for labor incurred in repairing or replacing defective part(s).

THERE IS NO OTHER EXPRESS WARRANTY. IMPLIED WARRANTIES, INCLUDING THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY AND TO THE EXTENT PERMITTED BY LAW ANY AND ALL IMPLIED WARRANTIES ARE EXCLUDED. THIS IS THE EXCLUSIVE REMEDY AND LIABILITY FOR CONSEQUENTIAL AND INCIDENTAL DAMAGES UNDER ANY AND ALL WARRANTIES ARE EXCLUDED TO THE EXTENT EXCLUSION IS PERMITTED BY LAW. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, OR THE LIMITATION OR EXCLUSION OF CONSEQUENTIAL OR INCIDENTAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

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:

<table>
<thead>
<tr>
<th>Phone</th>
<th>Purchase Date</th>
<th>Serial #</th>
</tr>
</thead>
</table>

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.

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### 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.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Enforcement – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class B Radiated and Conducted Emissions</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonics IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Flicker IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD)</td>
<td>±6kV contact ±8kV air</td>
<td>±6kV contact ±8kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical Fast Transient/burst</td>
<td>±2kV on AC Mains</td>
<td>±2kV on AC Mains</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge</td>
<td>±1kV Differential ±2kV Common</td>
<td>±1kV Differential ±2kV Common</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&gt;95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 5 Cycles &gt;95% Dip for 5 Seconds</td>
<td>&gt;95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles &gt;95% Dip for 5 Seconds</td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8</td>
<td>3A/m</td>
<td>3A/m</td>
<td>Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>
| Conducted RF IEC 61000-4-6 | 3 Vrms from 150 kHz to 80 MHz | V1 = 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: 
\[ D = \frac{3.5\sqrt{V1}}{P} \] |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | E1 = 3V/m | \[ D = \frac{3.5\sqrt{E1}}{P} \] 80 to 800 MHz  
\[ D = \frac{7\sqrt{E1}}{P} \] 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 (V1 and E1). 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.

<table>
<thead>
<tr>
<th>Maximum Output Power (Watts)</th>
<th>Recommended Separation Distances for the device (meters)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>[ D = \frac{1.1667\sqrt{P}}{} ]</td>
</tr>
<tr>
<td>0.01</td>
<td>0.11667</td>
</tr>
<tr>
<td>0.1</td>
<td>0.36894</td>
</tr>
<tr>
<td>1</td>
<td>1.1667</td>
</tr>
<tr>
<td>10</td>
<td>3.6894</td>
</tr>
<tr>
<td>100</td>
<td>11.667</td>
</tr>
</tbody>
</table>

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.