PORTABLE SUCTION ASPIRATOR

PART NUMBER 758010

OPERATOR / MAINTENANCE MANUAL
The care-e-vac®3 is a portable medical aspirator to suction fluids or foreign bodies from a patient. The medical device may be powered by a 100-240 VAC outlet or 12 VDC source. It is equipped with an internal battery. The primary intended use of the care-e-vac 3 is to aspirate saliva, mucous, vomitous or other aspirant from the mouth and or airway to allow adequate respiration or ventilation of the patient.

Dual power capabilities of the care-e-vac®3 is ideal for the following applications:

- Hospital crash cart suction
- Patient transport
- Surgi-center backup suction
- Emergency medical service
- Home health care/nursing homes

The care-e-vac®3’s suctioning capabilities are generated by a diaphragm pump. It comes equipped with a disposable in-line hydrophobic filter, 14” of tubing, and a disposable 800 cc collection canister.

This manual covers the care-e-vac®3 in the following sections:

I. Definitions and Symbols Legend Page 3
II. Instructions for Use Page 4
III. Maintenance Page 5
IV. Troubleshooting / Removal of Service Components Page 8
V. Device Specifications Page 9
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XV. Electromagnetic Compatibility Declarations Page 15

For additional information, please contact Ohio Medical Customer Service Department at 866-549-6446 or your local Ohio Medical Dealer.
This device should be used only by qualified medical personnel properly trained in medical suction techniques and in the operation of suction equipment. Improper use may cause injury. This operation manual should be read prior to the operation of this device.

WARNING: POSSIBLE EXPLOSION HAZARD IF USED IN THE PRESENCE OF FLAMABLE ANESTHETICS.

I. Definitions and Symbols

Legend

- **HIGH VACUUM HIGH FLOW** = High vacuum, high flow
- **Caution, consult instructions for use**
- **=** = Pump "Off"
- **=** = Pump "On"
- **=** = Type B Applied Part
- **=** = Fully charged battery
- **=** = Low battery
- **=** = Connected to AC power

**SN** Serial Number

Ohio Medical
Gurnee, IL 60031
www.ohiomedical.com

LED Lights

The care-e-vac®3 has been equipped with a set of three LED lights, which indicate the current status of the battery.

Green Light = OK. The unit will operate at its maximum performance.

WARNING: Red Light = LOW. The unit will continue to operate for less than 10 minutes and should be recharged immediately.

Amber Light = CHARGING / AC. Unit is properly connected to the power source. This light will remain illuminated as long as the unit is connected to the power source.
II. INSTRUCTIONS FOR USE

Please perform the following initial tests to ensure that your care-e-vac® 3 is in good working order and that no damage has occurred during shipment.

A) Preliminary Check

1. Visually inspect unit for physical damage that may have occurred during shipping.

2. Start without A/C power, depress the “VAC” switch to turn the unit ON ☐ and listen to verify the pump starts and that the **Green LED** is on. If the red LED illuminates, recharge the battery per instructions in section II.C, Recharging Battery.

3. Occlude the vacuum port with your fingertip and adjust the regulator knob. Verify that the gauge reflects a change in vacuum level while turning the regulator knob. Also, verify the presence of vacuum at your fingertip. Adjust the regulator to full vacuum ensure the gauge indicates “FULL VAC”.

4. Connect the AC power cord to the proper electrical outlet. Verify that the unit is charging by ensuring the **Amber LED** is on.

5. The bottle bracket is adjustable to accept any collection device up to 1200 cc. The bottle bracket can be adjusted by placing the unit on its side and locating the plastic clamp, which secures the bracket. Using a Phillips head screwdriver, *loosen* (DO NOT REMOVE) the screws and adjust the bracket to the desired position. Retighten the screws.

The care-e-vac® 3 is designed to use any size collection device up to 1200 cc. However, if you are not using an Aeros disposable collection canister, make sure the collection device being used is equipped with a SAFETY OVERFLOW MECHANISM to protect the pump from accidental overflow.

Ensure that you have the appropriate collection device, suction tubing and aspirator tip (catheter) for patient use. The care-e-vac® 3 is now ready to be used.

B) Operating Instructions

1. Check the battery level by turning the unit on and verifying that the “OK” Green LED illuminates. Turn the unit off.

2. Ensure that the hydrophobic filter is in-line between the vacuum port of the care-e-vac® 3 and the vacuum port on the collection bottle. If using another canister that comes with a built-in filter, do not use external inline filter. Also, confirm the aspirating tip is connected to the patient port on the collection bottle.

3. Turn the care-e-vac® 3 on and occlude to set, pinch the patient tubing closed, to adjust the vacuum to the desired vacuum level by using the vacuum regulator knob. Set the vacuum level to the *least* amount of vacuum necessary to properly suction the patient.
4. Release the pinched tubing and proceed with the suction procedure.

**CAUTION:** When operating unit in battery mode, the user must monitor the LED’s to ensure enough battery power is left to finish procedure.

C) Recharging Battery

1. To recharge the battery, plug the AC power cord into its respective electrical outlet. Verify the **Amber LED** is on. **Charging times varies depending on the condition of the battery.**

2. It is recommended to discharge the battery down to almost no charge 2 times a year to optimize your battery performance and life.

D) Processing and Cleaning Instructions

1. **WARNING:** Please discard all contaminated parts after any suctioning procedure according to law, region / national, or your hospital policy requirements for the disposition of hazardous waste materials. These components may include the connection canister, in-line hydrophobic filter, and all suction tubing.

2. Wipe the surface of the unit clean with a mild antiseptic and a clean soft cloth. Do not allow any cleaning solution to spill into the vents on the unit.

3. Turn unit on to check the condition of the battery. If the “LOW” Red LED illuminates, recharge the battery. Verify the unit can regulate to “FULL VAC” as outlined in section II.A.3

4. Place a new collection canister, suction tubing and filter with the care-e-vac® 3.

III. Maintenance

**WARNING:** Never disassemble the care-e-vac® 3 when the power cord is connected to an electrical outlet.

To access the internal components of the care-e-vac® 3, place the unit right side up and remove the six (6) (Philips) screws located on the back side of the unit. Slide the two front and back covers away from each other.

A) Pump Cleaning

The heart of the care-e-vac® 3 is a diaphragm pump. Over time, foreign particles may accumulate on the internal parts from aerosolized aspirant. It is recommended that the pump head be disassembled and cleaned when a decrease performance is noticed. Preventative maintenance is recommended every six months depending on frequency of use.

**WARNING:** Remove device from A/C power source prior to cleaning.
1. Disconnect the pump wires from the printed circuit board (PCB), then disconnect all tubing from the pump output elbow.

2. Remove the three (3) (phillips) screws from the vibration bumpers. Also, remove the four (4) screws located on top of the pump head. Remove the pump head. This will expose the diaphragm.

3. Using a mild soap solution, wash the surface of the diaphragm. **DO NOT** allow any solution to ingress to the diaphragm and into the pump chamber.

   **CAUTION:** Never flush your pump with any liquid solution, as this may damage your pump.

   Wash the underside of the pump head with the same soap solution as used on the diaphragm.

4. Thoroughly dry with a soft cloth. Next, reassemble the pump head, reinstall, and tighten the four screws. Reconnect the pump wires to the PCB and all tubing to the pump and regulator and follow reverse order of disassembly. Ensure that your unit performs according to the Device Specifications Section.

**B) Vacuum Regulator Cleaning**

The suction regulator may accumulate aspirant after the pump has been in service for an extended period of time. When disassembling the pump for cleaning, it is suggested that the regulator also be cleaned as a preventative measure.

1. Remove the regulator by disconnecting the silastic tubing and loosen the locknut (make note of the orientation of all tubing and the regulator body).

2. Disassemble the regulator and wash all parts with a mild soap solution. Wipe all parts thoroughly dry with a piece of cotton cloth before reassembling the regulator. Reinstall and reconnect the tubing.

**C) Battery Replacement / Maintenance**

**CAUTION:** If the device is not to be used for long periods of time, the battery should be removed to prevent damage to the battery and device.

**CAUTION:** To ensure the proper life of the battery, please follow the steps provided below.

**WARNING:** Remove device from A/C power source prior to changing. Risk of Electric Shock.

A number of factors may affect the life of the battery, such as the frequency of use, the frequency of charging, proper battery maintenance and mechanical abuse. Ohio Medical recommends changing the battery every 3 years, depending on the frequency of use.
Inability to retain a charge is the most detectable sign of a deteriorated battery.

1. If unit is plugged in to AC outlet, remove from AC outlet. Disconnect wires from the battery terminals. Disconnect wire harness from power supply (see diagram below). When re-connecting ensure that BLACK wire is connected to the BLACK terminal (-) and the RED wire is connected to the RED terminal (+). Turn on the switch and verify that the pump will run to ensure proper placement of the battery wires. In addition, make sure IDT connector is placed in correct position.

2. Note the orientation of the battery being replaced.

D) WARNING: Decontamination

In the event that contaminated fluids have ingressed beyond the hydrophobic filter, follow the procedure outlined below. In addition, always use proper protective gear (i.e. rubber/latex gloves, goggles, etc.) when in contact with contaminated parts:

1. Remove the device from the AC power source prior to cleaning and clean the interior of the chassis.

2. Disconnect the battery from the PC board to prevent damaging the PC board.

3. Disinfect the unit using a mild surface disinfectant, such as a 10:1 mixture of water and bleach.

4. Depending on the amount of contamination ingression within the pump system, remove and replace, or clean, all affected components.
   a. Items that can be cleaned: Housing, Gauge and Regulator
   b. Items that must be replaced if exposed to fluids and contaminates: Tubing, Control Circuit, Power Supply, Pump, Switch.
5. Should the care-e-vac3 reach the end of its useful life, ensure unit is disposed of in accordance with all local, federal, and/or hospital policy requirements. Proper disposal of contaminated components will significantly minimize the risk of patient and/or user exposure.

*Warning: Replace fuse with 5mm x 20mm, 6.3A 250V fast acting fuse only. Using incorrect fuse may cause significant damage to equipment or system, and may cause a fire.

IV. TROUBLESHOOTING / REMOVAL OF SERVICE COMPONENTS

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>CAUSE</th>
<th>CORRECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump does not turn on when the &quot;VAC&quot; switch is depressed.</td>
<td>1. Battery is not charged. 2. Faulty electrical connections. 3. Damaged power supply or control board. 4. Pump is non-operational. 5. Blown fuse 6. Battery wires are on wrong terminals.</td>
<td>1. Charge battery. 2. Make sure that all wires are secured tightly on the lugs and the lugs themselves are secured on the terminals. 3. Replace appropriate component. 4. Replace the pump. 5. Replace the power supply and / or fuse* on control board. 6. Switch battery wires to proper terminals</td>
</tr>
<tr>
<td>Low or no vacuum on running unit.</td>
<td>1. Improper tubing connection or crimped tube in the system. 2. Mechanical shut-off is activated in the collection canister. 3. Regulator is dirty. 4. Faulty pump. 5. Collection canister improperly installed or defective.</td>
<td>1. Check all external vacuum parts for crimped tubing. If still no vacuum, check all internal tubing connections. 2. If the mechanical shut-off has been activated on a full canister, replace the canister. 3. Clean per the Vacuum Regulator Cleaning section. 4. Clean the pump per the Pump Cleaning Section or replace pump. 5. Check canister for any cracks. Verify that all ports on the canister lid are tight.</td>
</tr>
<tr>
<td>Battery will not hold a charge</td>
<td>1. Battery is old and cannot retain a charge. 2. Blown fuse 3. Faulty control board.</td>
<td>1. Replace battery per Battery Replacement section. 2. Replace power supply and / or fuse* on control board. 3. Replace control board.</td>
</tr>
<tr>
<td>Gauge does not register vacuum level.</td>
<td>1. Gauge is either not connected or is faulty. 2. Blockage in vacuum lines.</td>
<td>1. Check that tubing is properly connected between vacuum regulator and gauge. 2. Ensure the vacuum regulator is not completely turned off and that there are no obstructions in the line.</td>
</tr>
</tbody>
</table>
Removal of service components:

1. **Pump**: Follow directions outlined in pump cleaning - Section III.A.

2. **Power Supply**: Remove power supply from back housing using standard Phillips head screw driver by removing the four screws holding it in place.

3. **Control Circuit**: Remove control circuit from control bracket using a #2 Phillips head screw driver.

4. **Battery**: Follow directions outlined in Battery Replacement – Section III.C.

5. **Gauge**: Back out positioning screws from gauge bracket. Once gauge bracket is loose, hold both gauge and bracket and turn gauge counter-clockwise to remove.

6. **Canister Bracket**: Remove all six (6) cover screws and slide covers apart. Loosen screws that hold bracket in place. Slide bracket out and replace with new bracket.

7. **Silencer**: Remove all six (6) screws and slide covers apart. Unscrew silencer from pump using a 3/8” box wrench.

8. **Regulator**: Follow directions outlined in vacuum regulator cleaning – Section III.B.

V. Device Specifications

**PUMP**: 12 VDC oil-less diaphragm type

**PERFORMANCE**: Vacuum Range: 0 to 550 mmHg [0-21.7 inHg]
Free Air Flow: 50 L/min [1.8 cfm] for 60 minutes

**CONTROLS**: Vacuum Regulator: Rotary type on panel
Vacuum Gauge: Calibrated to 0-500 mmHg [20 inHg]

**ELECTRICAL RATING**: 100-240 VAC, 0.75A, 50/60Hz

**BATTERY**: 12V 5AH Rechargeable Sealed Lead Acid

**BATTERY OPERATING TIME**: 60 minutes (uninterrupted with fully charged battery)

**CHARGING TIME**: 6 hours to 85%, 8 hours to 100%

**COLLECTION DEVICE**: 800 cc disposable plastic with mechanical shut-off (1200 cc version is also available)
VI. 800 cc Suction Canister System
Operating Instructions

Intended Use: For the collection and disposal of aspirated fluids.

Directions for Use
1. Gently shake lid to verify shut-off mechanism moves freely.
2. Place lid on canister and press firmly around entire perimeter.
3. Apply pour spout cap firmly over pour spout.
4. Firmly attach vacuum tube to -vacuum port and attach patient tube patient port.
5. Check all connections for proper seal. Test the assembly for vacuum leaks by turning on vacuum source and occluding the patient tubing with -finger or thumb.
6. To prevent fluid contamination to vacuum system, make sure vacuum line is attached to vacuum port.

Disposal
1. Turn off vacuum source and disconnect all tubing.
2. Seal vacuum and patient ports with attached port caps.
3. Remove canister from bracket and transport to disposal area. Do not lift canister by lid. The weight of the contents may cause the lid to separate from the canister.
4. Dispose of according to hospital policy.

⚠ CAUTION
• Single Use Only. Do not attempt to clean, sterilize or reuse canister. Possible consequences of reuse include: 1) implosion, 2) fluid bypass, 3) exposure to bloodborne pathogens.
• Do not exceed vacuum level of 25" (640mm) Hg.
• Not recommended for use in liposuction procedures.
• Do not apply continuous vacuum longer than 24 hours.
• Not intended as a measuring device, only for general reference, not specific measurement.
• Canister contents are considered potentially hazardous. Use appropriate PPE and handle accordingly.
• ☑ Check expiration date on canister for use-by-date (if applicable).
• ☑ Store in a dark place. Long term exposure to light may compromise product performance and result in breakage during use.

Loss of Vacuum: Check that vacuum is on, canister is properly sealed, and that all connections are tight and tubing is not kinked. If loss continues, replace canister.

Report any product malfunctions or complaints to Ohio Medical Customer Service Department.
VII. OSHA Hazard Communications Standard

OSHA HAZARD COMMUNICATION STANDARD 29CFR Section 1910.1200
OSHA BLOODBORNE PATHOGEN STANDARD 29 CFR Section 1910.1030

Dear Customer:

The Code of Federal Regulations (CFR) requires us to inform our customers who utilize our products in processes which contaminate them with either radioactive, biological, toxic or hazardous chemical substances, the following information:

Our facility does not have the ability to properly identify all the possible hazardous substances which could be present in our products returned for service. Since we cannot properly identify all hazards, we do not have the protective equipment and means to safely repair these products when returned for service.

Therefore, if product has been contaminated with radiological, biological, toxic or hazardous chemical substances, we cannot accept it for service at any of our facilities. Prior to the return of used product a request for a Security Declaration form is required. This form is filled out and sent back with the used product. This declaration informs the service department that the product returned, possesses no health or safety risks due to contamination by radioactive material, biological substances or hazardous chemicals.

If there are any questions pertaining to this subject, please call our Customer Service Department at (866) 549-6446.

Thank you for your cooperation.

OHIO MEDICAL
1111 Lakeside Drive
Gurnee, Illinois 60031
VIII. WARRANTY

OHIO MEDICAL warrants its Portable Suction Machines to be free from any defects in workmanship and materials as of the date they are shipped to the original purchaser.

For a period of three (3) years from the date on which the same shall have been delivered to the original purchaser, OHIO MEDICAL will repair or replace at its sole discretion any PORTABLE SUC- TION MACHINE which is proven to be defective in either workmanship or material.

All warranty determinations will be made by OHIO MEDICAL, and its responsibility shall be limited to providing in its sole discretion, new or similar rebuilt replacement parts to replace any component part found to be defective within the three year period.

This warranty covers only failures due to defects in workmanship or materials, which occur during normal use. It does not cover failures due to damage, which occurs in shipment, or failures, which result from accident, misuse, abuse, neglect, mishandling, alteration, misapplication, or damage that may be attributable to acts of God. Similarly this warranty does not apply to units that are re-sold or rented to others by the original purchaser. This warranty gives you specific rights. You may have other rights, which may vary from state to state.

To obtain service within the three year period, first contact your authorized OHIO MEDICAL dealer or OHIO MEDICAL Customer Service Department. Before returning any unit to the factory proper return authorization must first be obtained from the OHIO MEDICAL Customer Service Department.

Labor to repair any unit proved to be defective within the three year period will be provided at no charge for any unit returned to our factory adequately packaged and insured with shipping costs prepaid. Standard surface freight shipping costs to return the unit to the original purchaser will be paid by OHIO MEDICAL.

Any product returned must be free from contamination by toxic or hazardous substances in accordance with OSHA HAZARD COMMUNICATION STANDARD 29 CFR, Section 1910.1200 and OSHA BLOOD BORNE PATHOGEN STANDARD 29 CFR, Section 1910.1030. Decontamination of items prior to their return is the responsibility of the customer. In the event a returned item is found to be contaminated, it shall be regarded as regulated waste and disposed of and no credit for the item shall be issued to the customer.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. OHIO MEDICAL SHALL NOT BE LIABLE FOR INCIDENTAL, COLLATERAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

Outside of the United States, a different warranty may apply. For details please contact your authorized Ohio Medical dealer or the Customer Service Department.
### IX. ACCESSORIES

<table>
<thead>
<tr>
<th>PART</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>749144</td>
<td>REPLACEMENT SEALED LEAD ACID BATTERY</td>
</tr>
<tr>
<td>758007</td>
<td>CRASH CART MOUNT ADAPTER KIT</td>
</tr>
<tr>
<td>AI2557ASY</td>
<td>CRASH CART MOUNT (ALSO REQUIRES 758007)</td>
</tr>
<tr>
<td>AI2580000</td>
<td>FLOOR STAND (ALSO REQUIRES 758007)</td>
</tr>
<tr>
<td>AI4080000</td>
<td>CANISTER, COLLECTION, 800cc</td>
</tr>
<tr>
<td>AI4080010</td>
<td>CANISTER ONLY REPL. KIT, 800 cc, LID INCL., PACKAGE OF 10</td>
</tr>
<tr>
<td>AI4080025</td>
<td>CANISTER ONLY REPL. KIT, 800 cc, LID INCL, PACKAGE OF 25</td>
</tr>
<tr>
<td>AI4120000</td>
<td>CANISTER, COLLECTION, 1200 cc</td>
</tr>
<tr>
<td>AI4120010</td>
<td>CANISTER ONLY REPL. KIT, 1200 cc, LID INCL., PACKAGE OF 10</td>
</tr>
<tr>
<td>AI4120025</td>
<td>CANISTER ONLY REPL. KIT, 1200 cc, LID INCL., PACKAGE OF 25</td>
</tr>
<tr>
<td>751102</td>
<td>FILTER, HYDROPHOBIC W/ 14&quot; TUBING</td>
</tr>
<tr>
<td>749002</td>
<td>TIP, YANKAUER SUCTION</td>
</tr>
<tr>
<td>750810</td>
<td>KIT, 800 cc ASPIRATING CHANGE-OUT, CASE OF 10</td>
</tr>
<tr>
<td>750825</td>
<td>KIT, 800 cc ASPIRATING CHANGE-OUT, CASE OF 25</td>
</tr>
<tr>
<td>749003</td>
<td>TUBING, CONNECTING 72&quot;, 1/4&quot;</td>
</tr>
</tbody>
</table>

### X. SERVICE PARTS

<table>
<thead>
<tr>
<th>PART#</th>
<th>DESCRIPTION</th>
<th>QTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>758853</td>
<td>CEV3 Control PCB Kit</td>
<td>1</td>
</tr>
<tr>
<td>751106</td>
<td>Power Supply</td>
<td>1</td>
</tr>
<tr>
<td>758850</td>
<td>CEV3 Pump Kit Thomas</td>
<td>1</td>
</tr>
<tr>
<td>758852</td>
<td>CEV3 Battery Kit</td>
<td>1</td>
</tr>
<tr>
<td>754041</td>
<td>Gauge, 0-500mm Hg</td>
<td>1</td>
</tr>
<tr>
<td>758001</td>
<td>Bracket, Canister</td>
<td>1</td>
</tr>
<tr>
<td>758032</td>
<td>Silencer</td>
<td>1</td>
</tr>
<tr>
<td>758854</td>
<td>CEV3 Regulator Kit</td>
<td>1</td>
</tr>
<tr>
<td>758851</td>
<td>CEV3 Pump Kit GAST</td>
<td>1</td>
</tr>
</tbody>
</table>

**WARNING:** The use of accessories, service parts, and/or cables, other than those listed above, may result in increased electromagnetic emissions and/or decreased electromagnetic immunity of the equipment or system.
XI. **EMC Information:**

The care-e-vac®3 device meets the following EMC/EMI requirements for medical devices:

IEC 60601-1-2

**CAUTION:** Medical electrical equipment needs special precautions regarding 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. (See page 16)

XII. **Environmental Conditions:**

Specifications:

<table>
<thead>
<tr>
<th>Specification</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage Temperature Range</td>
<td>-40°C to 60°C (-40°F to 140°F)</td>
</tr>
<tr>
<td>Storage Relative Humidity Range</td>
<td>40% to 70% Non-Condensing</td>
</tr>
<tr>
<td>Pressure</td>
<td>50-106 kPa</td>
</tr>
<tr>
<td>Operating Temperature Range</td>
<td>-20°C to 50°C (-4°F to 122°F)</td>
</tr>
<tr>
<td>Operating Relative Humidity</td>
<td>95% Non-Condensing</td>
</tr>
</tbody>
</table>

XIII. **General Warnings**

1. To reduce the risk of electric shock, do not remove cover. Refer servicing to qualified personnel.
2. Risk of fire. Replace fuse as marked.
3. To insure proper grounding reliability, connect to "HOSPITAL GRADE" receptacle or equivalent.
4. The care-e-vac®3 device is powered by an AC power source or by a 12 VDC battery. Disconnecting main source does not disconnect battery.

XIV. **Battery Recycling and Disposal**

A used battery is a valuable resource. Insulate the battery terminals and dispose the battery by taking it to a battery recycling center.
### XV. Electromagnetic Compatibility Declarations for care-e-vac 3

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment: Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions</td>
<td>Group 1</td>
<td>The care-e-vac 3 uses RF energy only for its internal function. Therefore, it’s RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>Harmonic Emissions</td>
<td>Class A</td>
<td>The care-e-vac 3 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage Fluctuations/Flicker Emissions</td>
<td>Compiles</td>
<td>The care-e-vac 3 is intended for use in the electromagnetic environment specified below. The user of the care-e-vac 3 should assure that it is used in such an environment.</td>
</tr>
</tbody>
</table>

#### Guidance and Manufacturer’s Declaration - Electromagnetic Emissions

The care-e-vac 3 is intended for use in the electromagnetic environment specified below. The user of the care-e-vac 3 should assure that it is used in such an environment.

<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>Electromagnetic Emission</td>
<td>16 kV contact</td>
<td>&gt;6 V/m</td>
<td>Floors should be wood concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Discharge (ESD) IEC 61000-4-2</td>
<td>12 kV for power supply lines</td>
<td>&gt;1 kV for input/output lines</td>
<td>Maintains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Electrical Fast Transient/Burst IEC 61000-4-4</td>
<td>23 kV line(s) to line(s)</td>
<td>&gt;5 kV line(s) to earth</td>
<td>Maintains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>23 kV line(s) to line(s)</td>
<td>&gt;1 kV line(s) to line(s)</td>
<td>Maintains 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</td>
<td>60% dip in U(t)</td>
<td>&gt;60% dip in U(t) for 5 cycles</td>
<td>Maintains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>50% dip in U(t)</td>
<td>&gt;50% dip in U(t) for 5 cycles</td>
<td>Maintains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Power Frequency</td>
<td>3 A/m</td>
<td>&gt;3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Magnetic Field</td>
<td>2 V/m</td>
<td>&gt;2 V/m</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the care-e-vac 3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td>3 V/m</td>
<td>&gt;3 V/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Calculated RF</td>
<td>3 V/m</td>
<td>&gt;3 V/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 kHz to 80 MHz</td>
<td>&gt;150 kHz to 80 MHz</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the care-e-vac 3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>80 MHz to 2,5 GHz</td>
<td>&gt;80 MHz to 2,5 GHz</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the care-e-vac 3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>3 V/m</td>
<td>&gt;3 V/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Calculated RF</td>
<td>3 V/m</td>
<td>&gt;3 V/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>80 MHz to 2,5 GHz</td>
<td>&gt;80 MHz to 2,5 GHz</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the care-e-vac 3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
</tbody>
</table>

Note: 1/ U(t) is the a.c. mains voltage prior to application of the test level.

Note 2: At 80 MHz and 800 MHz, the higher frequency range applies.

** Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the care-e-vac 3 is used exceeds the applicable RF compliance level above, the care-e-vac 3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the care-e-vac 3.

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

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### Recommended Separation Distances Between Portable and Mobile Communications Equipment and the care-e-vac 3

The care-e-vac 3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the care-e-vac 3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the care-e-vac 3 as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation Distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 800 MHz</td>
<td>800 MHz to 2,5 GHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.12</td>
</tr>
<tr>
<td>0.38</td>
<td>0.12</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>3.8</td>
</tr>
<tr>
<td>20</td>
<td>3.8</td>
</tr>
<tr>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where Pr is the maximum output power rating 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.