

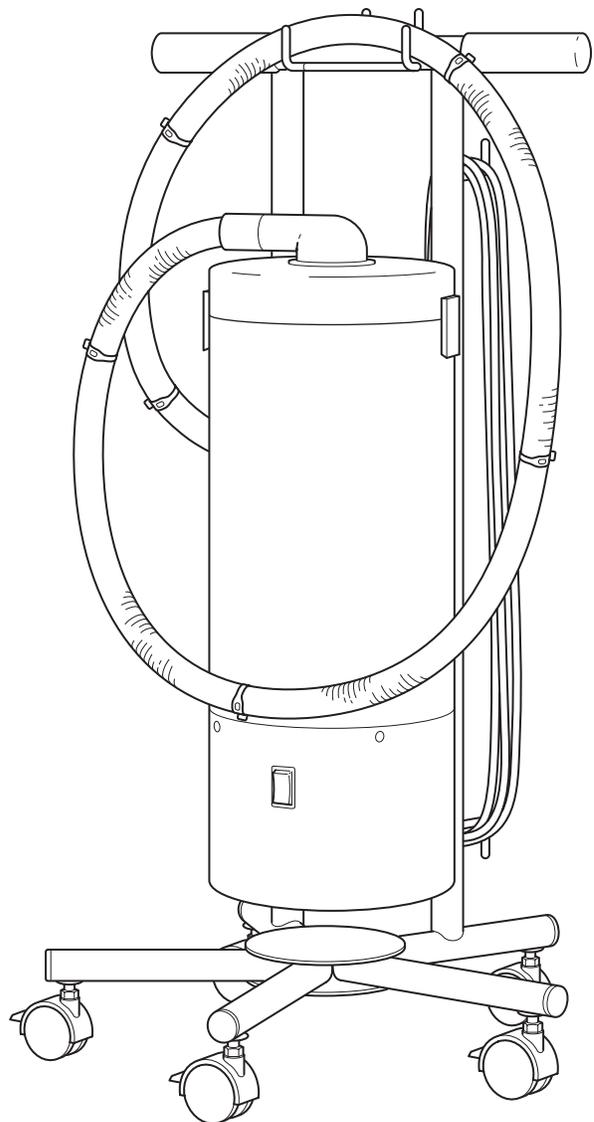
<p><i>Note: This portion of the document should not appear on produced Labels or IFUs.</i></p> <p>Stryker Instruments (269) 323-7700 (800) 253-3210</p>	<p>Dimensions: 8.5 inch (width) x 11 inch Booklet</p>	<p>Color/Material/Finish: Color Graphics on White Background 20# Bond or Equivalent</p>	<p>Label Stock: N/A</p>	
			<p>Description/Type: Instructions For Use</p>	
			<p>Part Number: 0986-001-011</p>	<p>Rev. R</p>

REF 0986-000-000

0996-000-000

REF 0987-000-000

R_x ONLY



Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the safe and effective use of your product. This manual may be used by in-service trainers, physicians, nurses, surgical technologists, biomedical equipment technicians, and central supply/sterile processing technicians. Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

For additional information, especially safety information, or in-service training, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

Indications For Use

The Stryker CastVac is intended to be used with a Stryker Cast Cutter. The CastVac simultaneously suctions dust and chips as cast material is cut.

Contraindications

None known.

For Use With

This section describes system components that must be used with the equipment described in this manual to create a safe and effective system.

DESCRIPTION	REF
Cast Cutter	0840-000-000
	0848-000-000
	0940-000-000
	0941-000-000



WARNING: ALWAYS connect the CastVac to a Cast Cutter with an appropriate voltage rating.

CASTVAC REF	VOLTAGE	CAST CUTTER REF
0986-000-000 0987-000-000	100-120 V ~	0840-000-000 0848-000-000 0940-000-000
0996-000-000	220-240 V ~	0941-000-000

User/Patient Safety



WARNINGS:

- Before using any system component, or any component compatible with this system, read and understand the instructions. Pay particular attention to WARNING information. Become familiar with the system components prior to use.
- Only trained and experienced healthcare professionals should use this equipment.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique used for each patient. Stryker, as a manufacturer, does not recommend surgical procedure or technique.
- Upon initial receipt and before each use, operate the equipment and inspect each component for damage. DO NOT use any equipment if damage is apparent or the inspection criteria are not met. See the *Inspection, Testing, and Maintenance* section.
- Only individuals trained and experienced in the maintenance of reusable medical devices should install, inspect, service, and test this equipment as described in this manual.
- DO NOT modify any system component or accessory.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- ALWAYS position the equipment so that the power cord plug may be easily disconnected from the power supply.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen or nitrous oxide.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like this system. Install and place this system into service according to the EMC information contained in this manual. Portable and mobile RF communications equipment can affect the function of this system.

Accessories



WARNINGS:

- Use only Stryker-approved system components and accessories, unless otherwise specified. Failure to comply may result in fire, electric shock, or injury.
- Using other electronic components and accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.

NOTE: For a complete list of accessories, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

This section describes system components that may be ordered to replace original equipment that is damaged, worn, or must be replaced. This section may also contain optional components used with the system.

The following Stryker-approved accessories are sold separately:

DESCRIPTION	REF
CastVac Mobile Stand	0989-000-000
High Performance Filter Cartridge	0986-500-000
Vacuum Hose with Cord Clips	0986-001-030
Vacuum Hose (to connect CastVac REF 0986-000-000 to Cast Cutter 0840-000-000)	0986-840-000
Adaptor Hose with Cord (to connect CastVac REF 0986-000-000 to Cast Cutter REF 0848-000-000)	0986-848-000

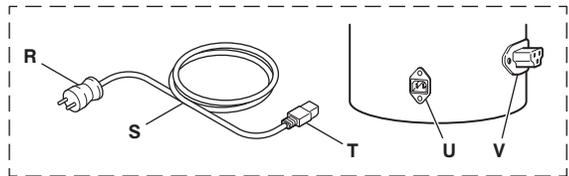
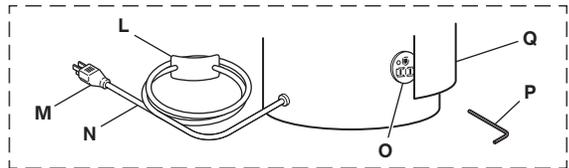
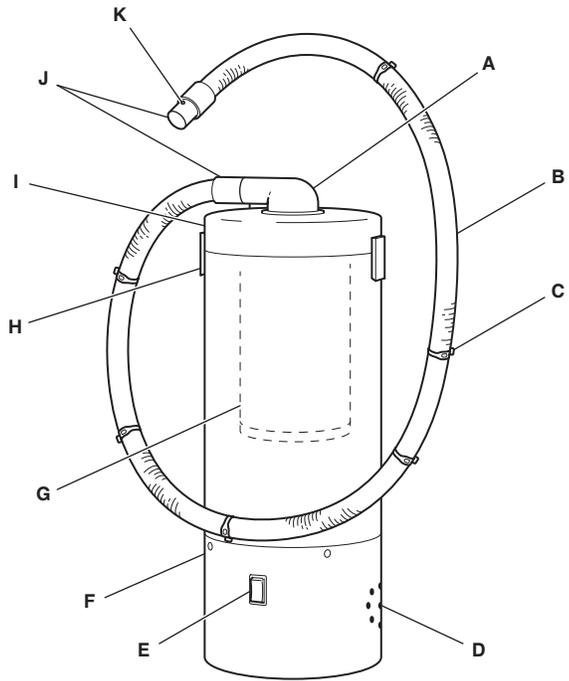
Definitions

The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

SYMBOL	DEFINITION
	Standby Mode
	Off (for part of CastVac only)
	On (for part of CastVac only)
	CastVac
	Cast Cutter
	Alternating current (AC)
	Non-ionizing electromagnetic radiation
	Caution
	General warning sign
	Refer to instruction manual/booklet
	Consult instructions for use
	Protective earth (ground)
	This symbol is intended to alert service personnel of the presence of voltage that may cause injury or fatal electric shock. Disconnect the device from the electrical supply before servicing.

Features

CastVac



A	Hose Connector
B	Vacuum Hose
C	Cast Cutter Power Cord Strap (6)
D	Exhaust Port
E	Function Switch
F	Canister
G	High Performance Filter Cartridge
H	Latch (2)
I	Lid
J	Hose Cuff (2)
K	Button (2)

Model REF 0986-000-000 and 0987-000-000 Only:

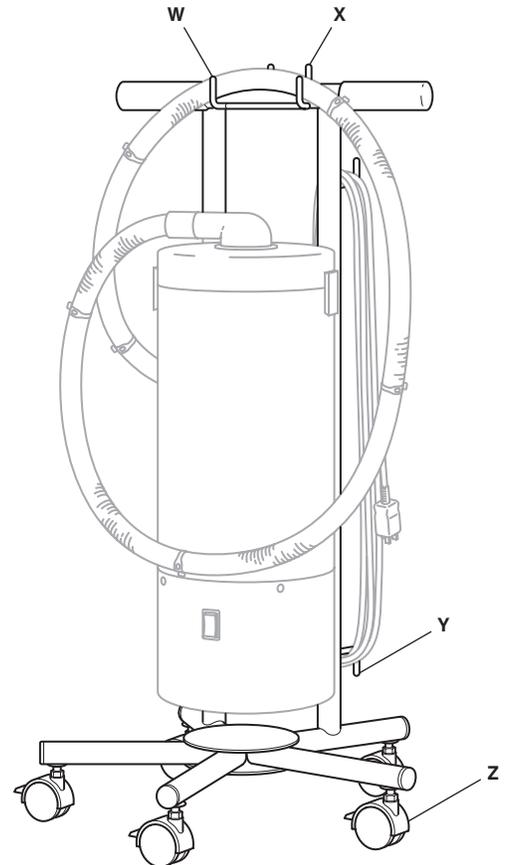
L	Power Cord Tag
M	Power Cord Plug
N	Power Cord
O	Power Outlet (AC power source for Stryker Cast Cutter use only)
P	Hex Key Wrench, 3.2 mm [1/8 inch]
Q	Outlet Cover

Model REF 0996-000-000 Only:

R	Power Source Cord Plug
S	Power Source Cord
T	Appliance Inlet Connector Plug
U	Appliance Inlet Connector
V	Power Outlet (AC power source for Stryker Cast Cutter use only)

CastVac Mobile Stand

NOTE: The CastVac Mobile Stand is supplied with CastVac REF 0986-000-000 and 0996-000-000 only.

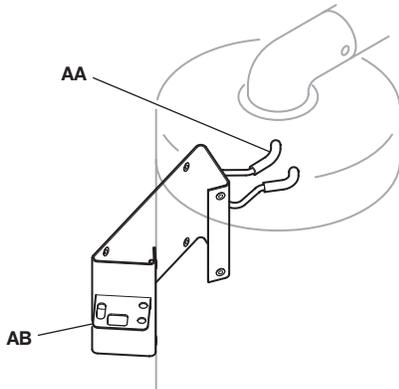


W	Vacuum Hose Hook (2)
X	Cast Cutter Hook (2)
Y	Power Cord Hook (2)
Z	Locking Caster (5)

CastVac Wall Mount Bracket

NOTES:

- The CastVac Wall Mount Bracket is supplied with CastVac REF 0987-000-000 only.
- For installation instructions and more information, see the instructions for use supplied with the CastVac Wall Mount Bracket.



AA	Cast Cutter Hook (2)
AB	Tool Bracket

Function Switch

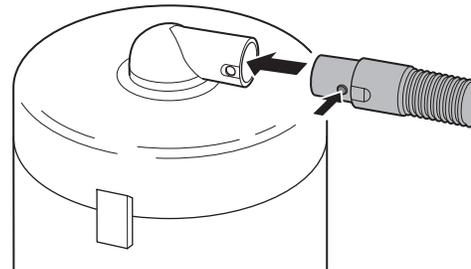
	<p>Standby Mode – When a Cast Cutter is connected to the power outlet, CastVac operation is controlled by the Cast Cutter function switch. The CastVac will operate only when the Cast Cutter function switch is set to the standard or high speed mode.</p> <p>NOTE: In standby mode, CastVac REF 0996-000-000 will continue to operate for 10 seconds after the Cast Cutter is turned off.</p>
	<p>Off – The CastVac will not operate.</p>
	<p>On – The CastVac will operate continuously.</p>

Instructions

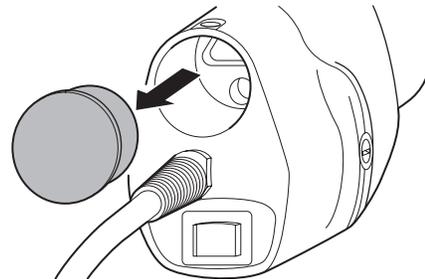
To Connect the CastVac to a Cast Cutter and a Power Source

NOTE: To provide optimum power, the vacuum hose must be securely connected to both the hose connector and the Cast Cutter.

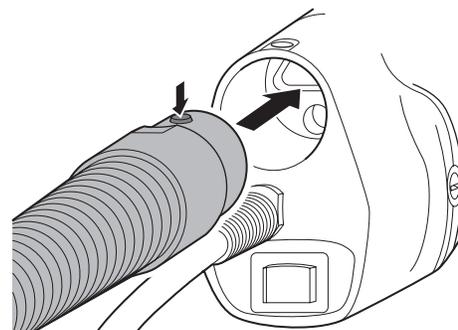
1. Depress the button on the hose cuff and align it with the hole in the hose connector.



2. Push the hose into the hose connector and release the button. Make sure the button is completely positioned and seated in the hole.
3. Remove the vacuum line cap from the Cast Cutter.

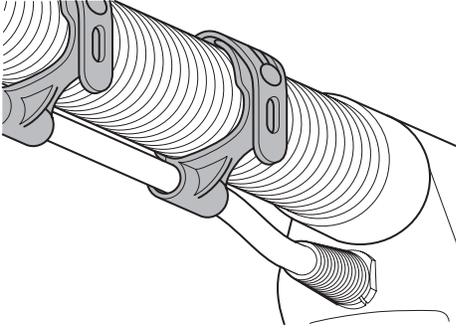


4. Depress the button on the hose cuff and align it with the hole in the Cast Cutter.



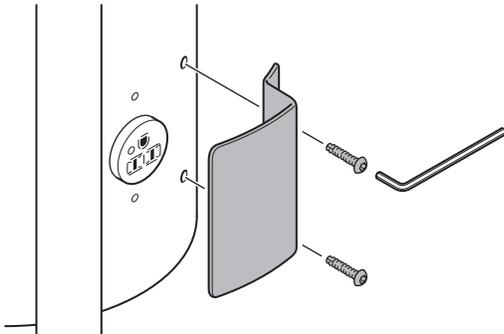
5. Push the hose into the Cast Cutter and release the button. Make sure the button is completely positioned and seated in the hole.

6. Attach the Cast Cutter power cord to the Cast Cutter power cord straps.



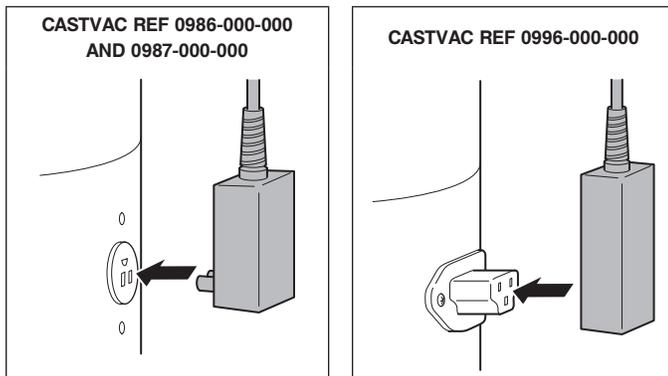
! WARNINGS:

- ALWAYS set the Cast Cutter function switch to the standby position before connecting the Cast Cutter power cord plug to the CastVac power outlet.
 - The CastVac power outlet is designed to accept the power cord plug from the Cast Cutter only. DO NOT connect other devices to the CastVac power outlet.
7. For CastVac REF 0986-000-000 and 0987-000-000 only, use the hex key wrench provided to remove the outlet cover from the canister.

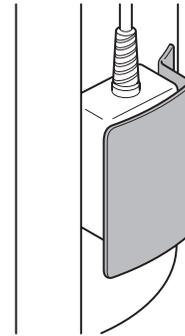


8. Connect the Cast Cutter power cord plug to the CastVac power outlet.

NOTE: See the instructions for use supplied with the Cast Cutter.



9. For CastVac REF 0986-000-000 and 0987-000-000 only, use the hex key wrench to reinstall the outlet cover.



10. Wrap any excess power cord length around the power cord hooks.

! WARNING: ALWAYS set the CastVac function switch to the off position before connecting the CastVac to a hospital-grade facility power outlet.

11. Set the CastVac function switch to the off position.
12. Connect the CastVac power cord plug to a hospital-grade facility power outlet.

NOTE: To connect CastVac REF 0996-000-000 to a hospital-grade facility power outlet, first connect the appliance inlet connector plug to the appliance inlet connector.

13. For CastVac REF 0986-000-000 and 0996-000-000 only, roll the CastVac mobile stand to a convenient location and lock the casters as required.

To Operate the CastVac

! WARNINGS:

- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- Before each use, make sure the equipment is completely dry. DO NOT use any equipment if moisture is present.
- DO NOT use the CastVac to vacuum wet material. The CastVac is designed to vacuum dry material only. Moisture or liquid inside the equipment may create an electric shock hazard.
- DO NOT operate this equipment with a damaged power cord or power cord plug.
- DO NOT modify the power cord or power cord plug.

CAUTION: ALWAYS place the power cord where it will not be stepped on, tripped over, or otherwise subjected to damage or stress.

1. Set the CastVac function switch to the on or standby mode position. See the *Features* section.
2. Use the Cast Cutter to section and remove a cast.

NOTE: See the instructions for use supplied with the Cast Cutter.

3. Upon completion, set the CastVac function switch to the off position.

To Disconnect the CastVac from the Power Source and the Cast Cutter



WARNINGS:

- ALWAYS set the CastVac function switch to the off position before disconnecting the CastVac from the facility power outlet.
- The CastVac function switch does not remove electrical power from the CastVac. To remove the electrical power, you must disconnect the power cord plug from the facility power outlet.

CAUTION: To reduce the risk of damage to the power cord, ALWAYS grasp the power cord plug, not the power cord, when disconnecting the CastVac.

1. Set the CastVac function switch to the off position.
2. Disconnect the CastVac power cord plug from the facility power outlet.
3. Disconnect the Cast Cutter power cord plug from the CastVac power outlet.
4. Remove the Cast Cutter power cord from the Cast Cutter power cord straps.
5. Depress the button on the hose cuff and pull the hose from the Cast Cutter.
6. Install the vacuum line cap onto the Cast Cutter.

Cleaning



WARNINGS:

- ALWAYS disconnect the power cord plug from the facility power outlet before cleaning the equipment. Failure to comply may cause fire, electric shock, or injury.
- DO NOT immerse or soak any component of the equipment in liquid. DO NOT allow moisture or liquid to soak into electrical plugs, receptacles, or openings. Moisture or liquid inside the equipment may create an electric shock hazard.
- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.

1. Disconnect the power cord plug from the facility power outlet.
2. Wipe the external surfaces of the equipment with a soft cloth moistened with a non-abrasive, mild detergent and water.
3. Thoroughly dry the equipment with a soft, absorbent cloth.

Inspection, Testing, and Maintenance



WARNINGS:

- Only individuals trained and experienced in the maintenance of reusable medical devices should inspect, test, and maintain this equipment.
- DO NOT disassemble or service this equipment, unless otherwise specified.
- ALWAYS disconnect the power cord plug from the facility power outlet before performing maintenance procedures on the equipment. Failure to comply may cause fire, electric shock, or injury.

NOTES:

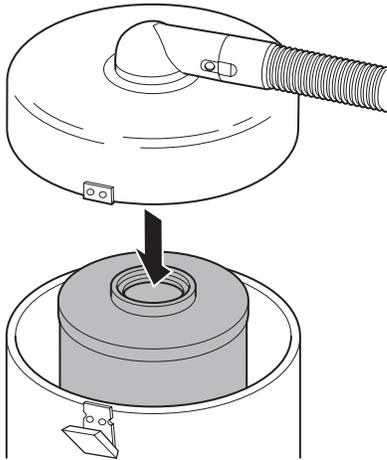
- Maintenance documentation for this equipment is available upon request to Stryker-authorized service personnel only.
- For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

INTERVAL	ACTION	INSPECTION CRITERIA
Upon initial receipt and before each use.	Inspect the equipment.	If damage or excessive wear is apparent, contact Stryker for repair.
		If any components are loose or missing, contact Stryker for repair.
	Inspect the power cord and/or power source cord.	If cracks, cuts, or damage is apparent, contact Stryker for repair.
	Operate the equipment.	If unusual sound, excessive noise, or vibration is apparent, contact Stryker for repair.
As required.	Inspect the filter cartridge.	If the filter cartridge is full or damaged, replace the filter cartridge. See the <i>To Replace the High Performance Filter Cartridge</i> section.

To Replace the High Performance Filter Cartridge

WARNING: ALWAYS disconnect the power cord plug from the facility power outlet before performing maintenance procedures on the equipment. Failure to comply may cause fire, electric shock, or injury.

1. Disconnect the power cord plug from the facility power outlet.
2. Open the two latches.
3. Remove the lid from the canister.
4. Pull and twist the hose connector to remove the filter cartridge from the lid. Dispose of the filter cartridge.
5. Place a filter cartridge in the approximate center of the canister, with the filter cartridge opening facing up.



6. Place the lid over the canister so that the bottom of the hose connector is aligned with the filter cartridge opening.
7. Press the lid down and twist the hose connector to connect the filter cartridge.
8. Close the two latches.

Storage and Handling

CAUTION: ALWAYS store the equipment within the specified environmental condition values throughout its useful life. See the *Specifications* section.

To ensure the longevity, performance and safety of this equipment, use of the original packaging material is recommended when storing or transporting this equipment.

Disposal/Recycle

WARNING: ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.



To comply with European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU, this device should be collected separately for recycling. Do not dispose of as unsorted municipal waste. Contact local distributor for disposal information. Ensure infected equipment is decontaminated prior to recycling.

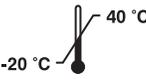
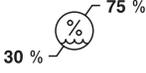
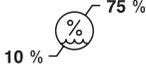
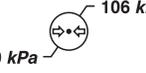
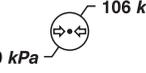
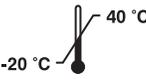
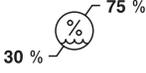
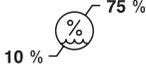
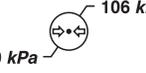
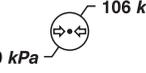
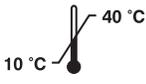
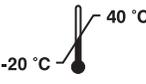
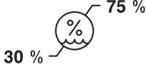
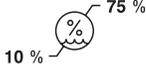
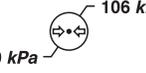
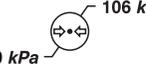
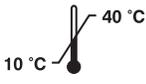
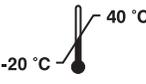
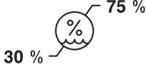
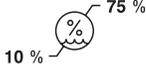
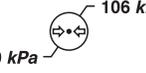
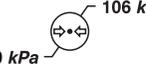
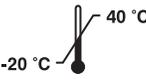
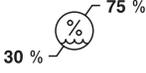
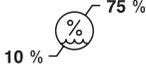
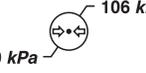
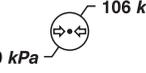
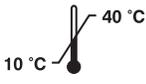
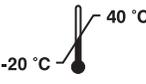
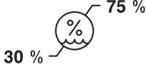
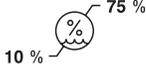
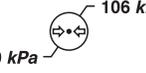
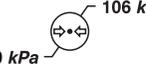
Troubleshooting

WARNING: DO NOT disassemble or service this equipment, unless otherwise specified. Failure to comply may cause fire, electric shock, or injury.

NOTE: For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

PROBLEM	CAUSE	SOLUTION
The CastVac does not operate.	The CastVac is not connected to facility power.	See the <i>To Connect the CastVac</i> section.
	The CastVac function switch is in the off position.	Set the CastVac function switch to the on or standby position.
Dust is emitted from the exhaust port or function switch.	The filter cartridge is not installed.	Install a filter cartridge. See the <i>Inspection, Testing, and Maintenance</i> section.
	The filter cartridge is full or damaged.	Replace the filter cartridge. See the <i>Inspection, Testing, and Maintenance</i> section.
The level of suction is reduced.	The vacuum hose is blocked with debris.	Remove the debris from the vacuum hose.
	The filter cartridge is blocked with debris.	Remove the blockage. If the filter cartridge is full, replace the filter cartridge. See the <i>Inspection, Testing, and Maintenance</i> section.
	Inadequate exhaust ventilation.	Remove the obstruction from the exhaust port.
The standby mode does not work.	Electrical circuit failure.	Return the CastVac to Stryker for repair.
The CastVac stops operating without being turned off.	The thermal protective auto-reset switch has been activated.	Let the CastVac cool and try again. If the problem persists, return the CastVac to Stryker for repair.
	The filter cartridge is blocked with debris.	Replace the filter cartridge. See the <i>Inspection, Testing, and Maintenance</i> section.
The equipment experiences sporadic electrical interference.	Electrical noise is present.	Turn off all electrical equipment not in use.
		Relocate electrical equipment; increase spatial distance between devices.
		Connect electrical equipment to different facility power outlets.

Specifications

Model:	Stryker CastVac with Mobile Stand (REF 0986-000-000) Stryker CastVac with Wall Mount Bracket (REF 0987-000-000)	Stryker CastVac with Mobile Stand (REF 0996-000-000)																		
Electrical:	100-120 V ~, 50-60 Hz, 8.5 A input	220-240 V ~, 50-60 Hz, 4.75 A input																		
Power Cord/Power Source Cord:	3.6 m [12 ft] length, fitted with NEMA 5-15P hospital-grade plug	2.5 m [8.2 ft] length, fitted with CEE 7/7 Schucko plug																		
Power Outlet:	NEMA 5-15R hospital-grade, 100-120 V ~ (for use with Cast Cutter REF 0840-000-000, 0848-000-000, and 0940-000-000 only)	NEMA 5-15R hospital-grade, 220-240 V ~, Maximum load 0.75 A (for use with Cast Cutter REF 0941-000-000 only)																		
Dimensions:	62.0 cm [24.4 inch] height (canister) 22.2 cm [8.75 inch] diameter (canister)	62.0 cm [24.4 inch] height (canister) 22.2 cm [8.75 inch] diameter (canister)																		
Mass:	6.1 kg [13.5 lb] (canister)	6.1 kg [13.5 lb] (canister)																		
Vacuum Hose:	2.4 m [8 ft] length	2.4 m [8 ft] length																		
Mode of Operation:	Continuous	Continuous																		
Equipment Type:	Class I	Class I																		
Ingress Protection:	IPX0	IPX0																		
Means of Isolation from Supply Mains:	Disconnection of the power cord plug from the facility power outlet	Disconnection of the power cord plug from the facility power outlet																		
Environmental Conditions:	<table border="0"> <tr> <td style="text-align: center;">Operation</td> <td style="text-align: center;">Storage and Transportation</td> </tr> <tr> <td style="text-align: center;">  <p>10 °C — 40 °C</p> </td> <td style="text-align: center;">  <p>-20 °C — 40 °C</p> </td> </tr> <tr> <td style="text-align: center;">  <p>30 % — 75 %</p> </td> <td style="text-align: center;">  <p>10 % — 75 %</p> </td> </tr> <tr> <td style="text-align: center;">  <p>70 kPa — 106 kPa</p> </td> <td style="text-align: center;">  <p>50 kPa — 106 kPa</p> </td> </tr> </table>		Operation	Storage and Transportation	 <p>10 °C — 40 °C</p>	 <p>-20 °C — 40 °C</p>	 <p>30 % — 75 %</p>	 <p>10 % — 75 %</p>	 <p>70 kPa — 106 kPa</p>	 <p>50 kPa — 106 kPa</p>	<table border="0"> <tr> <td style="text-align: center;">Operation</td> <td style="text-align: center;">Storage and Transportation</td> </tr> <tr> <td style="text-align: center;">  <p>10 °C — 40 °C</p> </td> <td style="text-align: center;">  <p>-20 °C — 40 °C</p> </td> </tr> <tr> <td style="text-align: center;">  <p>30 % — 75 %</p> </td> <td style="text-align: center;">  <p>10 % — 75 %</p> </td> </tr> <tr> <td style="text-align: center;">  <p>70 kPa — 106 kPa</p> </td> <td style="text-align: center;">  <p>50 kPa — 106 kPa</p> </td> </tr> </table>		Operation	Storage and Transportation	 <p>10 °C — 40 °C</p>	 <p>-20 °C — 40 °C</p>	 <p>30 % — 75 %</p>	 <p>10 % — 75 %</p>	 <p>70 kPa — 106 kPa</p>	 <p>50 kPa — 106 kPa</p>
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Model:	Stryker CastVac with Mobile Stand (REF 0986-000-000) Stryker CastVac with Wall Mount Bracket (REF 0987-000-000)	Stryker CastVac with Mobile Stand (REF 0996-000-000)
European Conformity:	Not applicable	
Product Safety Certification:	 CSA International Canadian Standards Association (CSA) CAN/CSA-C22.2 No. 601.1-M90, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety</i> Underwriters Laboratories (UL) UL 60601-1, <i>Medical Electrical Equipment, Part 1: General Requirements for Safety – First Edition</i> ; Revisions through and including April 26, 2006 International Electrotechnical Commission (IEC) IEC 60601-1:1988, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety - Second Edition</i> ; Amendment 1 (1991); Amendment 2 (1995); Corrigendum 1 (1995) European Committee for Electrotechnical Standardization (CENELEC) EN 60601-1:1990, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety</i> ; Amendment 1 (1993); Amendment 11 (1993); Amendment 12 (1993); Amendment 2 (1995); Amendment 13 (1996)	Canadian Standards Association (CSA) CAN/CSA-C22.2 No. 601.1-M90, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety</i> Underwriters Laboratories (UL) UL 60601-1, <i>Medical Electrical Equipment, Part 1: General Requirements for Safety – First Edition</i> ; Revisions through and including April 26, 2006 International Electrotechnical Commission (IEC) IEC 60601-1:2005, <i>Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance</i> ; IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007) IEC 60601-1:1988, <i>Medical Electrical Equipment – Part 1: General Requirements for Safety - Second Edition</i> ; Amendment 1 (1991); Amendment 2 (1995); Corrigendum 1 (1995) Canadian Standards Association (CSA) CAN/CSA-C22.2 No. 60601-1:08, <i>Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance</i> American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ANSI/AAMI ES60601-1:2005, <i>Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance</i> ; Consolidated Reprint (2009); Amendment 2 (2010) European Committee for Electrotechnical Standardization (CENELEC) EN 60601-1:2006, <i>Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance</i> ; IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010); CENELEC Amendment A11 (2011)

Guidance and manufacturer's declaration - electromagnetic emissions		
The CastVac (REF 0996-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the CastVac (REF 0996-000-000) should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The CastVac (REF 0996-000-000) 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 A	The CastVac (REF 0996-000-000) is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The CastVac (REF 0996-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the CastVac (REF 0996-000-000) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the CastVac (REF 0996-000-000), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ 150 kHz to 80 MHz $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz 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.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CastVac (REF 0996-000-000) is used exceeds the applicable RF compliance level above, the CastVac (REF 0996-000-000) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating CastVac (REF 0996-000-000).

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

Guidance and manufacturer's declaration - electromagnetic immunity			
The CastVac (REF 0996-000-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the CastVac (REF 0996-000-000) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±2, ±4, ±6 kV contact ±2, ±4, ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	95% Reduction (10ms) 60% Reduction (100ms) 30% Reduction (500ms) 95% Reduction (5s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CastVac (REF 0996-000-000) requires continued operation during power mains interruptions, it is recommended that the CastVac (REF 0996-000-000) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m @ 50Hz CRT 1A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the alternating current mains voltage prior to application of the test level.

Recommended separation distances between portable and mobile RF communications equipment and the CastVac (REF 0996-000-000)			
The CastVac (REF 0996-000-000) is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CastVac (REF 0996-000-000) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CastVac (REF 0996-000-000) as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

ES/DE/FR/IT/NL/EL 0986-001-715
JA/ZH/KO 0986-001-725
SV/DA/FI/PT/NO/PL 0986-001-730



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