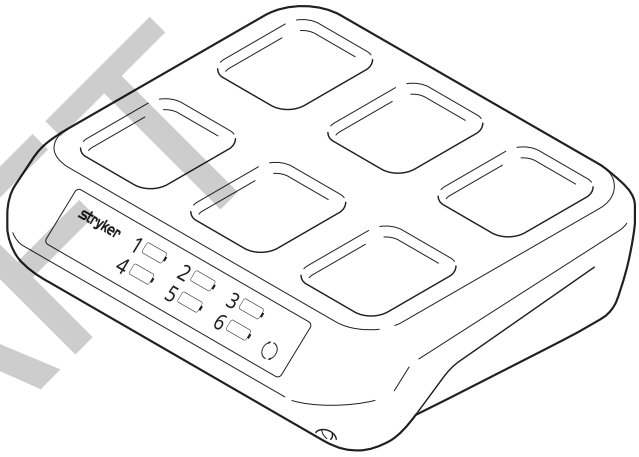
System 9 Sterile Battery Charger

REF 9110-120-000

Instructions For Use

R_X ONLY

CE



(01)07613327553505

ENGLISH (EN)

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Important Information

Using this Manual

This manual is the most comprehensive source of information for the safe, effective, and compliant use and/or maintenance of your product. This product is intended for use by trained and experienced healthcare professionals only. Read and understand this manual before using the product or any component compatible with the product. Contact Stryker for training as needed.

This manual is a permanent part of the product. Keep this manual for future reference.

The following signal words may be used throughout this manual:

WARNING - Highlights a safety-related issue. Always comply with this information to prevent patient and/or healthcare staff injury.

CAUTION - Highlights a product reliability issue. Always comply with this information to prevent product damage.

NOTE - Supplements and/or clarifies procedural information.

Contact Information

- Stryker Representative
- 1-269-323-7700, 1-800-253-3210
- inst.stryker.cs@stryker.com
- www.stryker.com

NOTE - The user and/or patient should report any serious product-related incident to both the manufacturer and the Competent Authority of the European Member State where the user and/or patient is established.

Indications For Use

The Stryker System 9 Sterile Battery Charger is intended to inductively charge appropriate Stryker Battery Packs. The batteries can be charged while in sterile blue wrap or in their native form by placing them directly onto the charger.

Contraindications

None known.

For Use With

WARNING

- Use only Stryker-approved equipment, unless otherwise specified.
- Use only Stryker-approved electronic components and accessories. Failure to comply may result in degraded performance, increased electromagnetic emissions, or decreased electromagnetic immunity of the system.

NOTE - Contact Stryker for a complete list of accessories.

To obtain a safe combination, the charger must be used with System 9 batteries and a Stryker-approved power cord.

Description	REF
System 9 Battery Pack, Small	9212-000-000
System 9 Battery Pack, Large	9215-000-000
Power cord	0996-851-0XX series

NOTE - For power cord options that meet country-specific requirements and are acceptable for use with the charger, see *Specifications*.

Safety Directives

WARNING

- Healthcare professionals should be thoroughly familiar with the instructions for use and the operation of this product prior to use.
- Always inspect the product and all system components for damage upon initial receipt and before each use. Do not use the product if damage is apparent.
- Do not use this product 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 this product. Install and/or put this product into service per the EMC information contained in this manual. Portable and mobile radio frequency (RF) equipment can affect the function of this product.
- Always operate the product within the specified environmental condition values; see *Specifications*.
- The System 9 Sterile Battery Charger is limited to professional use within a professional healthcare environment, excluding near high frequency (HF) surgical equipment and accessories; see *Electromagnetic Compatibility*.
- Do not modify any equipment.

CAUTION - Do not use this product to charge anything except compatible Stryker System 9 batteries.

Definitions

NOTE - Additional product and/or labeling symbols are defined in the Symbol Definition Chart supplied with the product.

See also *Disposal/Recycle*.

Symbol	Definition (Source)
	Fuse (IEC 60417 Ref 5016)
	Protective earth; protective ground (IEC 60417 Ref 5019)

Additional Definitions

Symbol	Definition (Source)
	Manufacturer (BS EN ISO 15223-1 5.1.1)
EC REP	Authorized representative in the European Community (BS EN ISO 15223-1 5.1.2)
	Date of manufacture (BS EN ISO 15223-1 5.1.3)
REF	Catalog number (BS EN ISO 15223-1 5.1.6)
SN	Serial number (BS EN ISO 15223-1 5.1.7)
	Consult instructions for use (BS EN ISO 15223-1 5.4.3)
	Caution (BS EN ISO 15223-1 5.4.4)
MD	Medical device (BS EN ISO 15223-1 5.7.7)
R_x ONLY	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. (CFR 801.109(b)[1])
	Non-ionizing electromagnetic radiation (IEC 60417 5140)
	Importer (BS EN ISO 15223-1 5.1.8)

Product Overview

Charger

The System 9 Sterile Battery Charger (Figure 1) has 6 bays to charge System 9 Battery Packs (large or small) through inductive (wireless) charging. The battery packs can be charged before sterilization while (1) unwrapped or after sterilization while (2) wrapped in sterilization wrap. The charger has an illuminated display panel that shows charger, bay, and battery status, including cycle counts.

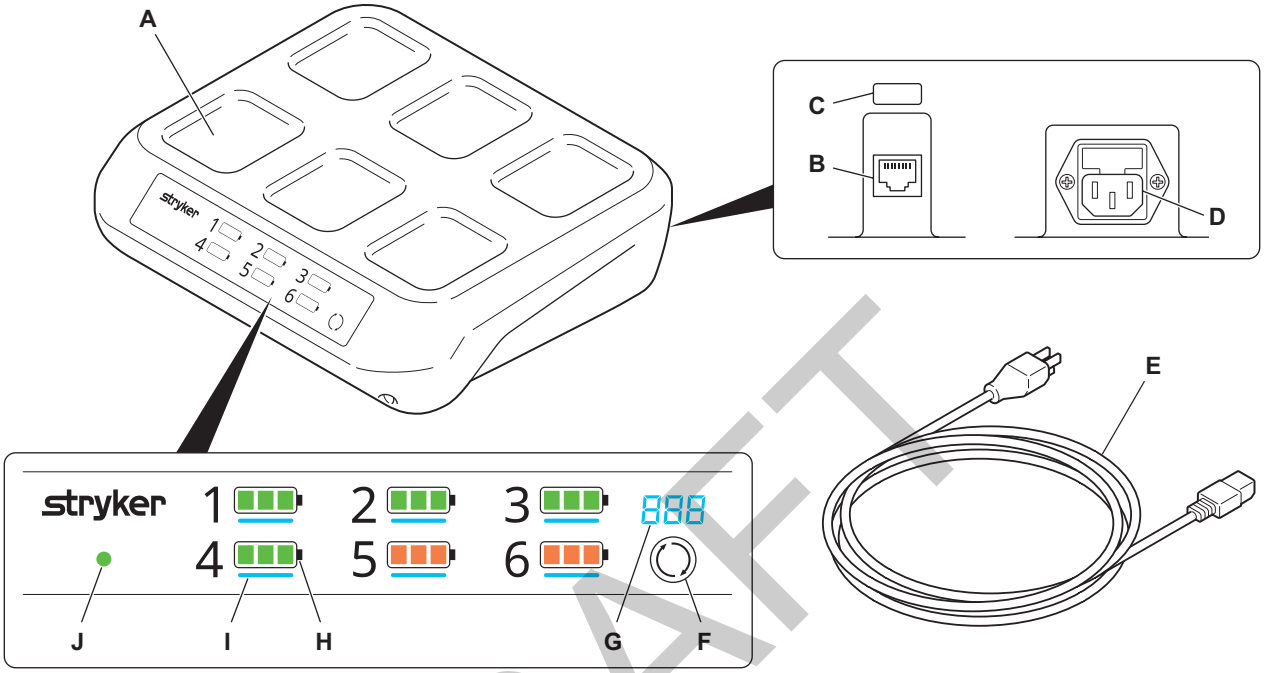


Figure 1 – Charger features

Feature	Description
A	**Charger Bay (6)** – Charge receptacles designed to accept only System 9 Sterile Batteries; see *For Use With*. Each charger bay has a corresponding battery status indicator (H) on the display panel, numbered 1 through 6.
B	**Ethernet Port** – Used to export device usage data from the charger to Stryker via Stryker's Cloud; see Figure 2.
C	**MAC ID Label** – Media Access Control Identifier (MAC Address).
D	**Power Cord Receptacle** – Allows connection of the power cord.
E	**Power Cord** – Connects the charger to a facility power receptacle.
F	**Cycle Button** – Press the cycle button to: ▪ Choose the power mode during initial setup; see *To Connect the Charger*. ▪ Wake up the charger from standby (asleep) mode; see *Power Modes*. ▪ Toggle through the charger bays to see the cycle count for each battery; see *To Check Battery Cycle Count*.
G	**Cycle Count** – The number of charge cycles on the selected battery.
H	**Battery Status Indicator** – Shows the status of the battery; see *State of Charge*.
I	**Bay Status Indicator** – Bar that illuminates below the selected battery status indicator(s).
J	**Power Mode Indicator** – Illuminates when the charger is connected to a facility power receptacle. The color indicates the charger power mode; see *Power Modes*.

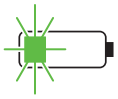
Power Modes

The color of the power mode indicator tells you whether the charger is operating in eco mode or standard mode. To set or change the power mode, see *To Set the Power Mode*.

Indicator Color	Mode Description
Blue 	**Eco (economy) mode** – Power saving mode that allows the charger to go on standby (asleep) when: ▪ all batteries are charged, ▪ no errors are detected, and ▪ there is no activity for 180 minutes. The power mode indicator flashes blue when the charger is on standby; see *To Set the Power Mode*.
Green 	**Standard mode** – Regular operating mode. The charger will never go on standby (asleep) while in standard mode.

State of Charge

The battery status indicator uses 3 light bars to display the state of charge for each battery. A flashing bar indicates the rising state of charge.

Light Bars	Description
	**Fully Charged** – 3 solid green bars
	**Medium Charge** – 2 solid green bars, 1 flashing green bar
	**Low Charge** – 1 solid green bar, 1 flashing green bar
	**No Charge** – 1 flashing green bar

Error State

An amber light(s) on the display panel indicates an error state for the battery or charger.

Light Color	Description
	**Error** – See the *Troubleshooting* section.

Getting Started

To Connect the Charger

WARNING

- To avoid the risk of electric shock, always connect this product to a hospital-grade, facility power receptacle with protective earth (ground).
- Always use the appropriate charger to charge batteries.
- Do not operate the charger using a voltage inconsistent with the rating on the back of the unit.
- Do not operate the charger with a damaged power cord or plug.
- Do not modify the power cord.
- Always position the product so that the power cord can be easily disconnected.
- Do not place the charger within the sterile field.
- Do not touch the battery charger and the patient simultaneously. Failure to comply may cause electrical shock.
- Metal objects between battery pack and charger may get hot. To avoid the risk of burns, do not put any metal device on the charger.

CAUTION

- Do not put any near field communication (NFC) enabled device on the charger.
- Always position the power cord where it will not be stepped on, tripped over, or otherwise subjected to damage or stress.

1. Use the power cord to connect the battery charger to a hospital-grade, facility power receptacle (Figure 2).
2. OPTIONAL: Use an Ethernet cable (not supplied) at least 3 meters in length to connect the Ethernet port to a facility Ethernet receptacle.
   NOTE
   - Confirm with a facility IT representative that the Ethernet receptacle has access to the Internet.
   - See the network requirements in the *Specifications* section.
   - For more information, contact your Stryker sales representative.

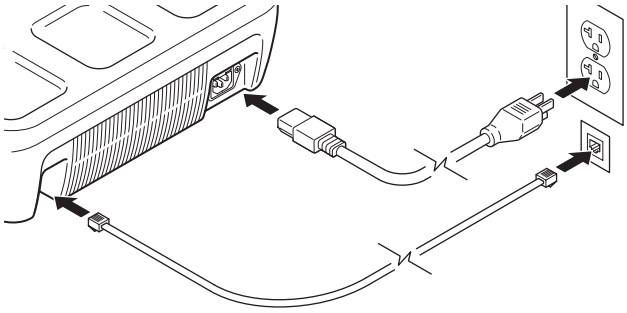


Figure 2 – Charger connections

To Set the Power Mode

Upon initial connection to facility power, the power mode indicator illuminates solid green to indicate that the charger is operating in standard mode.

1. Choose the ongoing power mode for the charger. See *Power Modes* for mode descriptions.
   - To operate the charger in standard mode, no further action is needed. The charger is ready to use.
   - To operate the charger in eco (economy) mode, hold the cycle button for 7 seconds. The power mode indicator will turn solid blue.

NOTE - Change the power mode any time by holding the cycle button for 7 seconds.

Using Your Product

To Charge a Battery

CAUTION - When battery packs require postsurgical sterilization, always allow the battery packs to cool for one hour before charging. Excess heat buildup from sterilization and charging will damage the battery packs.

NOTE

- For maximum capacity, charge the battery between each use.
- A typical charging sequence takes between 5 and 30 minutes. A fully expended, large battery may take up to 150 minutes to charge. Ensure the battery is at room temperature before charging.

1. If operating in eco (economy) mode and the charger is on standby (the power mode indicator is flashing blue), first press the cycle button to wake up the charger.
2. Load the clean, dry battery(s) onto the charger in any one of the following configurations:

   Before sterilization (Figure 3):
   - individually, unwrapped

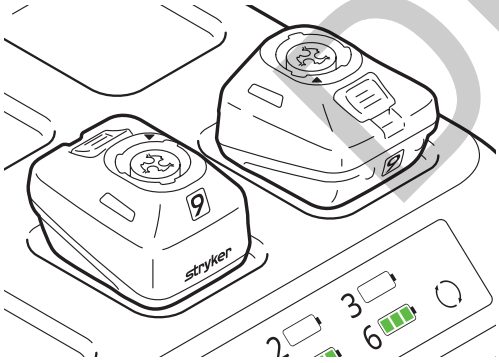


Figure 3 – Load battery before sterilization

   After sterilization (Figure 4):
   - individually, wrapped in sterilization wrap

NOTE - For wrapped battery packs, ensure the sterilization wrap is:
- approved by an applicable regulatory body
- labeled for use with the validated sterilization parameters in the *System 9 Processing Instructions* manual supplied with the handpiece
- wrapped flat and tight across the bottom of the battery

WARNING - If a metal-backed sterilization indicator is included in the sterilization wrap, make sure the indicator is not positioned near the bottom (charger side) of the battery. Failure to comply will result in a metal detection error, the battery will not charge, and the metal object may get hot; see *Troubleshooting*.

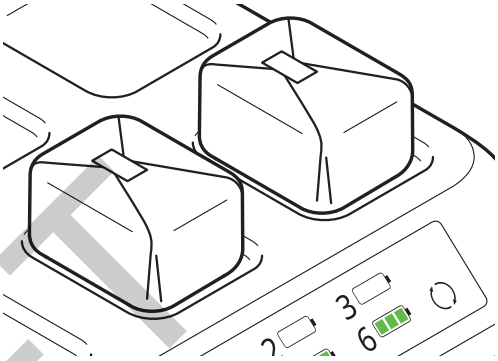


Figure 4 – Load battery after sterilization

3. Make sure the flat bottom of the battery pack is completely situated within the charger bay and fully in contact with the charger surface (Figure 5).

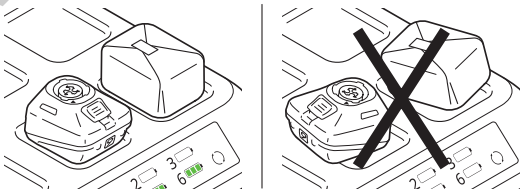


Figure 5 – Ensure correct battery placement

4. Upon contact with the battery, the battery status indicator for the occupied charger bay flashes green while the battery communicates with the charger.

NOTE - If the charger detects a misaligned battery or a metal object between the battery pack and the charger bay, the battery status indicator for that bay displays 3 solid amber bars, and the bay status indicator (bar) flashes amber; see *Troubleshooting*.

5. After a few seconds, the battery status indicator displays the state of charge; see *State of Charge*.

6. Once the charging sequence begins, the target state of charge bar on the battery status indicator flashes continuously to indicate that charging is in process (Figure 6).

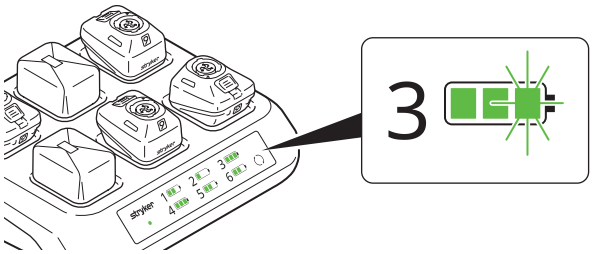


Figure 6 – Charge in process

7. When the battery is fully charged, the battery status indicator displays 3 solid green bars (Figure 7).

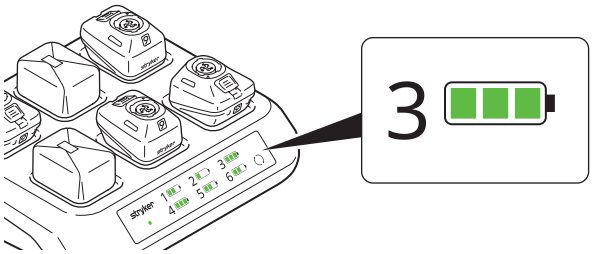


Figure 7 – Charge complete

To Check Battery Cycle Count

1. Press the cycle button to select a battery. The bay status indicator for that battery illuminates solid blue (Figure 8).
2. The number of charge cycles for the selected battery displays in blue above the cycle button.

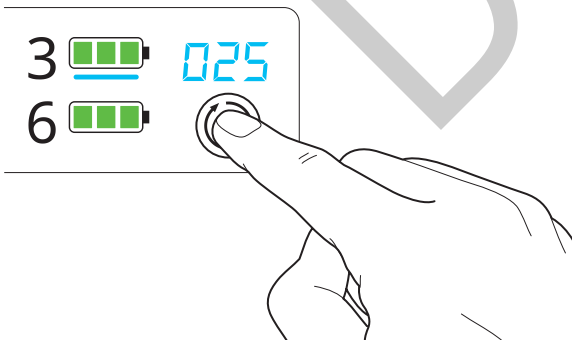


Figure 8 – Check cycle count

To Disconnect the Battery Charger

CAUTION

- To reduce the risk of damage to the power cord, always pull the power cord plug, not the power cord, when disconnecting the battery charger.
- Some power cords have a locking mechanism to prevent accidental disconnection. To remove a power cord with a locking mechanism, slide back the red locking tab.

1. Disconnect the battery charger from the facility power receptacle.
2. Disconnect the battery charger from the Ethernet receptacle.

After Use

Cleaning

WARNING - Before cleaning, always disconnect the power cord from the facility power receptacle and the battery charger to reduce the risk of electric shock.

CAUTION

- Do not immerse the product in liquid.
- Do not use solvents, lubricants, or other chemicals, including glutaraldehyde or similar chemical cleaners, unless otherwise specified.
- Do not allow liquid or moisture to enter any electrical connection or the cooling vents on the back of the charger.
- Do not sterilize the product.

1. Disconnect the power cord from the facility power receptacle and the battery charger.
2. Disconnect the Ethernet cable, if used, from the Ethernet port.
3. Wipe all external surfaces of the battery charger and power cord with a soft, non-linting cloth moistened with a prepared cleaning solution or non-abrasive hospital disinfectant and water.
4. Dry the equipment with a clean, non-linting cloth or medical-grade compressed air.
5. Inspect the battery charger and power cord for damage; see *Inspection*.

Inspection

WARNING

- Only individuals trained and experienced in the maintenance of reusable medical devices should inspect this equipment.
- Before inspection, always disconnect the power cord from the battery charger to reduce the risk of electric shock.
- Do not use any equipment if damage is apparent or the inspection criteria are not met.

NOTE

- If the equipment fails to meet the inspection criteria, contact Stryker for service.
- The useful life of this equipment is dependent upon many factors including, but not limited to, the method and duration of each use, and the handling of the equipment between uses.
- Routine inspection is the best method for determining the serviceable life span of the equipment.

Interval	Activity	Criteria
Upon initial receipt and before each use	Inspect the equipment	No damage or signs of wear
		No loose or missing components
		No cuts in the power cord
		No cracks in the housing

References

Storage and Handling

CAUTION

- Always store and transport the product within the specified environmental limitations.
- Always save the original packaging container for reuse. Failure to comply may result in damage during transport to the Stryker customer service center.

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 product at the end of its useful life.

SYMBOL	DEFINITION
	In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) as amended product 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.
	To comply with China RoHS Standard SJ/T 11364, this device has been marked with the environmentally-friendly use period (EFUP) number, measured in years. The device contains at least one of the listed hazardous substances above threshold.

China RoHS Disclosure Report

REF 9110-120-000

Part Name	Hazardous Substances					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr (VI))	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Electronic circuit boards and charger power supply	X	O	O	O	O	O

This table is prepared in accordance with the provisions of SJ/T11364.
O: Indicates that said hazardous substance contained in all of the homogenous materials for this part is below the limit requirement of GB/T26572.
X: Indicates that said hazardous substance contained in at least one of the homogenous materials used for this part is above the limit requirement of GB/T26572.

Troubleshooting

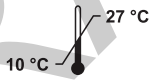
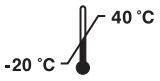
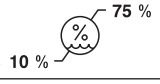
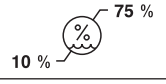
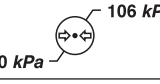
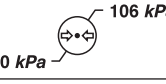
OBSERVATION	CORRECTIVE ACTION
The charger lights do not illuminate.	Reset the cord connections on the back of the battery charger and at the facility power receptacle; see *To Connect the Charger*. Have qualified personnel confirm that the facility power receptacle is working properly. If the charger remains unresponsive, contact Stryker for service.
All 6 bay status indicators flash amber to indicate a charger error. 	Reset the cord connections on the back of the battery charger and at the facility power receptacle; see *To Connect the Charger*. If the error persists, contact Stryker for service.
Battery error: All 3 bars of the battery status indicator illuminate solid amber while battery is in contact with charger. 	Remove the battery, wait 5 seconds, then reseat the battery in the charger bay. The bottom of the battery pack must be in full contact with the surface of the charger; see *To Charge a Battery.* Try a different battery. Try a different charger bay(s). If the battery pack is enclosed in sterilization wrap, ensure the battery pack is properly wrapped (see *To Charge a Battery)*, and the bottom of the battery pack is in full contact with the surface of the charger. If the error persists, contact Stryker for service.
Misaligned battery: Battery is not seated correctly on the charger; or Metal object detected: All 3 bars of the battery status indicator illuminate solid amber, and the bay status indicator flashes amber. or If the alignment of the battery and removal of any metal objects have been verified, then condensation may have accumulated inside the battery during processing. 	Remove the battery, wait 5 seconds, then reseat the battery in the charger bay. The bottom of the battery pack must be in full contact with the surface of the charger; see *To Charge a Battery.* Remove the metal object. **NOTE** - The metal object may be located inside the sterilization wrap, between the battery and charger. Try a different charger bay(s). Process the battery per the *Processing Instructions* supplied with the handpiece. After the processing is complete, allow the battery to cool for a minimum of one hour before charging. If the error persists, contact Stryker for service.
Bay error: The bay status indicator illuminates solid amber. 	Remove the battery from the charger bay. The bay is disabled. The remaining charger bays are still functional. Insert the battery into a different charger bay. Reset the cord connections on the back of the battery charger and at the facility power receptacle; see *To Connect the Charger*. If the error persists, contact Stryker for service.
The cycle count does not appear when you press the cycle button.	Contact Stryker for service.
The battery becomes unusually hot during use or while charging.	Return the battery to Stryker.
Sporadic electrical interference is experienced.	Turn off all electrical equipment not in use. Relocate electrical equipment; increase spatial distance. Install electrical equipment into different facility power receptacles.

Specifications

Charger	
Model:	System 9 Sterile Battery Charger
REF:	9110-120-000
Dimensions:	105 mm [4.1 inch] height, 363 mm [14.3 inch] width, 314 mm [12.4 inch] length
Mass:	4.4 kg [9.8 lb]
Material:	In accordance with the European REACH regulation and other environmental regulatory requirements, the charger contains the following substances that are identified as being above 0.1% w/w: Lead, CAS No. 7439-92-1; Lead monoxide (lead oxide), CAS No. 1317-36-8; and Diboron trioxide, CAS No. 1303-86-2; and 1-Methyl-2-Pyrrolidone (NMP), CAS No. 872-50-4. This declaration is made in good faith and is either based upon a technical evaluation, supplier data, and/or laboratory testing.
Mode of Operation:	Continuous Operation
Electrical Input:	~ 100-230 V, ˜50-60 Hz, 3.35 A
Fuse:	T 5A H, 250 V
Ingress Protection:	IPX0
Equipment Type:	Class I
Ground Type:	Protective earth ground
Means of Isolation from Supply Mains:	Disconnect the power cord from the battery charger power cord receptacle.
Network Requirements	
Purpose of the Connection:	Device Usage Data
Required Network Characteristics:	Standard TCP/IP over Ethernet (IEEE 802.3 10/100 Mbs)
Required Network Configuration:	DHCP server, Mask and Gateway provided by site IT admin; Access to Stryker's Cloud
Technical Specifications of the Connection:	Standard TCP/IP over Ethernet (IEEE 802.3 10/100 Mbs), utilized industry standard https (port 443) web services communication to Stryker's Cloud.
Intended Information Flow:	Device Usage Data
Hazardous Situations Resulting from a Failure of the Network:	None known. **CAUTION** – Subsequent changes to the IT network could introduce new risks and require additional analysis. The hospital IT admin should identify, analyze, evaluate, and control these risks. Changes to the IT network include: changes in network configuration, connection of additional items, disconnection of items, update of equipment, upgrade of equipment.
Wireless Power Transfer	
Frequency of Operation:	129.7 kHz
RF Bandwidth:	125.5-133.9 kHz
Modulation:	None
RF Field Strength:	10.64 dBuV/m at 3m
Near-field Communication (NFC)	
Frequency of Operation:	13.56 MHz
RF Bandwidth:	13.553-13.567 MHz
Modulation:	ASK
RF Field Strength:	19.41 dBuV/m at 30m

Power Cord (general)	
Ratings:	
Current:	10 A
Voltage (nominal):	250 VAC minimum
Frequency:	50-60 Hz
Temperature:	0 ˚C to 70 ˚C minimum
Flammability:	UL 94 V-2 minimum, IEC 60332-1
Conductor:	
Size:	3 X 1.00 mm^2 ≤ size < 3 X 1.50 mm^2
Material:	Copper
Connector Type:	IEC 60320 C13
Plug Type:	The facility power (mains) plug shall have a ground/earthing pin.
Cord:	
Type:	SJT, H05VV-F, HVCTF, RVV or equivalent (unshielded)
Length:	3.0 m, 2.5 m **NOTE** – The 2.5 m cord is not for use in Canada or the US.
Dielectric Withstand:	1500 VAC for 60 seconds between line and protective earth, and between neutral and protective earth
Certification:	All applicable in-country medical electrical requirements

Power Cord (country-specific)
The Canadian and US power supply cord shall have a tag or label in English and French indicating that “GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED ‘HOSPITAL ONLY’ OR ‘HOSPITAL GRADE’ ” or equivalent wording. **Agency Approval:** C SP US CSA Certified for Canada and US or c CLASSIFIED UL us UL Recognized for Canada and US.

Environmental Limitations	Operation	Storage and Transportation
Temperature:		
Humidity:		
Atmospheric Pressure:		

Wireless Notifications

For wireless communication technology, these statements apply to the countries as indicated:

Country/Mark	Notification
Canada	Contains IC: 4919A-9110120550 This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: (1) this device may not cause interference; (2) this device must accept any interference, including interference that may cause undesired operation of the device. L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage; (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement. To ensure compliance with FCC and ISED RF exposure requirements this device must be installed to provide a minimum of 20cm between the device and people. Pour garantir la conformité aux exigences d'exposition RF de la FCC et d'ISED Canada, cet appareil doit être installé de manière à laisser un minimum de 20 cm entre l'appareil et les personnes.
United States of America BC	Complies with California Energy Commission (CEC) Battery Charger System Appliance Regulation Contains FCC ID: Q9R-9110120550 This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. To ensure compliance with FCC and ISED RF exposure requirements this device must be installed to provide a minimum of 20cm between the device and people.

Electromagnetic Compatibility

WARNING - Do not stack or place equipment adjacent to the product. If such a configuration is necessary, observe the configuration to ensure that electromagnetic interference does not degrade performance.

Guidance and manufacturer's declaration - electromagnetic emissions		
The System 9 Sterile Battery Charger (REF 9110-120-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 9 Sterile Battery Charger (REF 9110-120-000) should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The System 9 Sterile Battery Charger (REF 9110-120-000) 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	**NOTE** – The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. The System 9 Sterile Battery Charger (REF 9110-120-000) 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	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The System 9 Sterile Battery Charger (REF 9110-120-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 9 Sterile Battery Charger (REF 9110-120-000) 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	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 20%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	±2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s) ±0.5, ±1, ±2 kV line(s) to earth	±0.5, ±1 kV line(s) to line(s) ±0.5, ±1, ±2 kV line(s) to earth	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 0% U_T (100% dip in U_T) for 0.5 cycle at 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚ 0% U_T (>100% dip in U_T) for 1 cycle at 0˚ 70% U_T (30% dip in U_T) for 25 & 30 cycles at 0˚ <5% U_T (>95% dip in U_T) for 5 s 0% U_T (100% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 0% U_T (100% dip in U_T) for 0.5 cycle at 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚ 0% U_T (>100% dip in U_T) for 1 cycle at 0˚ 70% U_T (30% dip in U_T) for 25 & 30 cycles at 0˚ <5% U_T (>95% dip in U_T) for 5 s 0% U_T (100% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the System 9 Sterile Battery Charger (REF 9110-120-000) requires continued operation during power mains interruptions, it is recommended that the System 9 Sterile Battery Charger (REF 9110-120-000) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m, 30 A/m	3 A/m, 30 A/m	Power frequency magnetic fields should be at levels characteristic 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.

Guidance and manufacturer's declaration - electromagnetic immunity			
The System 9 Sterile Battery Charger (REF 9110-120-000) is intended for use in the electromagnetic environment specified below. The customer or the user of the System 9 Sterile Battery Charger (REF 9110-120-000) 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 outside ISM bands 80% AM at 1 kHz 6 Vrms 150 kHz to 80 MHz in ISM bands 80% AM at 1 kHz	N/A	Portable and mobile RF equipment should be used no closer to any part of the System 9 Non- Sterile Battery Charger (REF 9110-120-000), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: 150 kHz to 80 MHz $d=1.17\sqrt{P}$ 80 MHz to 800 MHz $d=1.17\sqrt{P}$ 800 MHz to 2.7 GHz $d=2.33\sqrt{P}$ 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). **WARNING** - Portable RF equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System 9 Sterile Battery Charger (REF 9110-120-000), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. 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 80% AM at 1 kHz 27 V/m 385 MHz Pulse modulation 18 Hz, Maximum power 1.8 W 28 V/m 450 MHz, FM ± 5 kHz deviation, 1 kHz sine, Maximum power 2 W 9 V/m 710, 745, 780, 5240, 5500, 5785 MHz, Pulse modulation 217 Hz, Maximum power 0.2 W 28 V/m 810, 870, 930 MHz, Pulse modulation 18 Hz, Maximum power 2 W 28 V/m 1720, 1845, 1970, 2450 MHz, Pulse modulation 217 Hz, Maximum power 2 W	3 V/m 80 MHz to 2.5 GHz 80% AM at 1 kHz 27 V/m 385 MHz Pulse modulation 18 Hz, Maximum power 1.8 W 28 V/m 450 MHz, FM ± 5 kHz deviation, 1 kHz sine, Maximum power 2 W 9 V/m 710, 745, 780, 5240, 5500, 5785 MHz, Pulse modulation 217 Hz, Maximum power 0.2 W 28 V/m 810, 870, 930 MHz, Pulse modulation 18 Hz, Maximum power 2 W 28 V/m 1720, 1845, 1970, 2450 MHz, Pulse modulation 217 Hz, Maximum power 2 W	
Proximity magnetic fields IEC 61000-4-39	65 A/m 134.2 kHz, pulse modulation 2.1 kHz 7.5 A/m 13.56 MHz, pulse modulation 50 kHz	65 A/m 134.2 kHz, pulse modulation 2.1 kHz 7.5 A/m 13.56 MHz, pulse modulation 50 kHz	

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 System 9 Sterile Battery Charger (REF 9110-120-000) is used exceeds the applicable RF compliance level above, the System 9 Sterile Battery Charger (REF 9110-120-000) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System 9 Sterile Battery Charger (REF 9110-120-000).
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Certifications

Underwriters Laboratories Inc. certification mark for United States and Canada. These products were tested and meet medical electrical equipment certification requirements, including compliance with applicable 60601 series standards. For additional information, contact Stryker.

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