stryker

SurgiCount®+ System

Instructions For Use

Cradle

REF 0694-002-002

Reader

REF 0694-002-005

Stand

REF 0694-002-001

Alternative Cradle Mounts

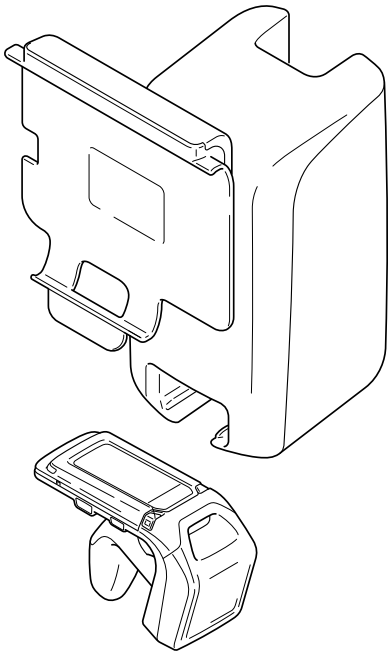
REF 0694-002-003

REF 0694-002-004

Disposables

REF 0694-002-010

REF 0694-002-006



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EN

700001138880 Rev-AC 2021-02

Table of Contents

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

Intended Users

This equipment is intended for use by physicians, nurses, surgical assistants, and biomedical equipment technicians.

Indications For Use

Refer to the instructions for use for the applicable Surgical Tablet software application.

Contraindications

Refer to the instructions for use for the applicable Surgical Tablet software application.

For Use With

WARNING

- 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, see *Electromagnetic Compatibility* (page 25).
- Use only Stryker-approved components and accessories, unless otherwise specified.

This product is intended for use with:

Components	REF
Surgical Tablet	0794-001-010
SurgiCount®+ Reader	0694-002-005
SurgiCount®+ Stand	0694-002-001

Accessories

Alternative Cradle Mounts	REF
SurgiCount®+ Cradle Wall Mount	0694-002-003
SurgiCount®+ Cradle Pole Mount	0694-002-004

Disposables	REF
SurgiCount®+ Sponge Counting Bag (QTY 250)	0694-002-010
SurgiCount®+ Reader Cover (QTY 90)	0694-002-006

Note - For ordering information, contact a Stryker sales representative.

Documentation

This table identifies documentation associated with the SurgiCount®+ System.

Instructions for Use	REF
Surgical Tablet	700000794727
SurgiCount®+ System (Cradle, Reader, Stand, Alternative Cradle Mounts, Disposables)	700001138880

Installation Guides (Mounting Options)	REF
SurgiCount®+ Stand	700001353738
SurgiCount®+ Cradle Wall Mount	700001130845
SurgiCount®+ Cradle Pole Mount	700001130854

Safety Directives

General Safety

WARNING

- Only healthcare professionals that are trained and experienced in the use of this medical device should operate this equipment, see *Intended Users* (page 2).
- Equipment is limited to professional use within a professional healthcare environment.
- Healthcare professionals should be thoroughly familiar with the instructions for use, handling characteristics, and the indicated, contraindicated, and intended uses of this equipment. Contact your Stryker sales representative or customer service for in-service training.
- 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 disassemble, modify, or repair this product without the authorization of the manufacturer. Contact Stryker for service.
- Always operate, store, and transport the equipment within the specified environment, see *Environmental Conditions* (page 24).
- Do not stare directly into the SurgiCount®+ Reader barcode scanner.

Electrical Safety

WARNING

- Take special precautions regarding electromagnetic compatibility (EMC) when using the SurgiCount®+ System. Install and place this medical electrical equipment into service according to the EMC information contained in this manual. Portable and mobile radiofrequency equipment and high frequency (HF) surgical equipment can affect the function of this medical electrical equipment, see *Electromagnetic Compatibility* (page 25).
- Always maintain a minimum separation distance of 6 inches [15 cm] from an in-use pacemaker and the UHF RFID antenna of the SurgiCount®+ Reader while in use. Failure to comply may cause interference with the pacemaker.

Battery Safety

WARNING

- Do not allow battery contacts to touch metal objects.
- The SurgiCount+ Cradle and SurgiCount+ Reader use lithium-ion batteries. To reduce the risk of fire or burns, do not disassemble, crush, burn, or puncture the batteries. For disposal/recycle information, see *Disposal/Recycle* (page 21).

Infection Control and Safety

WARNING

- Do not allow any equipment other than a properly prepared reader to enter the sterile field. Always prepare the reader for sterile use before using the device within the sterile field, see *Preparing the Reader for Sterile Use* (page 16). Failure to comply may cause infection and result in patient or healthcare staff injury.
- Do not contact the patient with the SurgiCount®+ Reader or SurgiCount®+ Reader Cover. Failure to comply may cause infection and result in patient or healthcare staff injury.
- Always clean and disinfect the equipment as indicated upon initial receipt and after before use. Failure to comply may cause infection and result in patient or healthcare staff injury. For cleaning and disinfection information, see *Cleaning and Disinfection* (page 18).

WARNING

- Always maintain a minimum separation distance of 9 inches [23 cm] from the head and torso of a person and the UHF RFID antenna of the SurgiCount®+ Reader while in use. Failure to comply may cause FCC RF exposure limits to be exceeded.
- The SurgiCount®+ System is MR unsafe. Do not use the system in an MR environment.

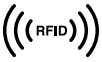
Acronyms

Acronym	Definition
CEC	California Energy Commission
EMC	ElectroMagnetic Compatibility
EPA	Environmental Protection Agency
FCC	Federal Communications Commission
HF	High Frequency
LAN	Local Area Network
LED	Light-Emitting Diode
MR	Magnetic Resonance
PPE	Personal Protection Equipment
RF	Radio Frequency
RFID	Radio Frequency IDentification
UHF	Ultra High Frequency
US EPA	United States Environmental Protection Agency
USB	Universal Serial Bus
WEEE	Waste Electrical and Electronic Equipment

Definitions

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

Labeling	
	Fragile
	Magnetic Resonance (MR)
	Crossed-Out Wheeled Bin Lithium-Ion
	Universal Recycling Lithium-Ion

SurgiCount+ Equipment Symbols and Definitions	
	UHF RFID Antenna
	USB Type-A
	Power Cord Hook Release Indicator

Product Overview

Cradle

The cradle facilitates communication between the tablet and the reader. Additionally, the cradle provides battery backup power to the system when disconnected from electrical power.

Cradle Mounting Options:

- SurgiCount+ Stand (recommended)
- SurgiCount+ Wall Mount (alternative)
- SurgiCount+ Pole Mount (alternative)

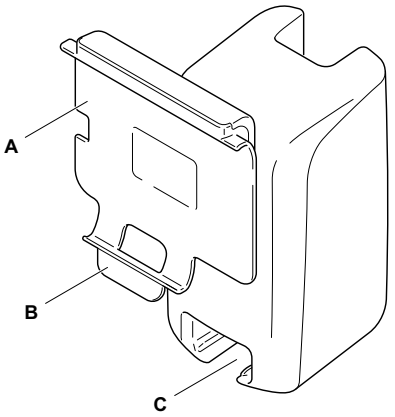


Figure 1 – Cradle (Front View)

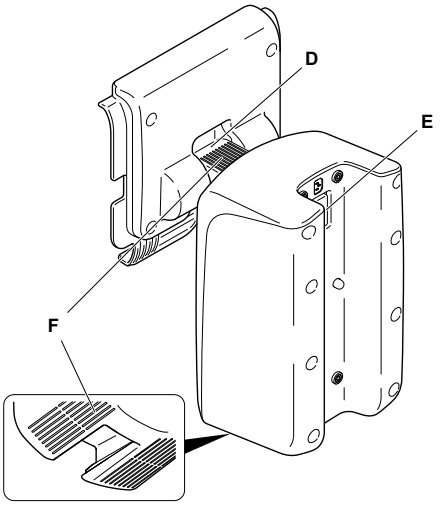


Figure 2 – Cradle (Rear View)

A	Tablet Dock	**D**	Tilt Adjustment
B	Insertion/Removal Tab	**E**	Power Cord Receptacle
C	Reader Dock	**F**	Vent Holes

Reader

The reader is a handheld battery powered device that provides UHF RFID and barcode functionality.

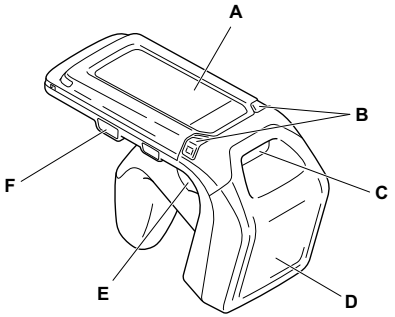


Figure 3 – Reader (Front View)

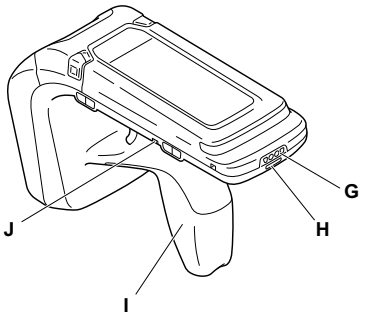


Figure 4 – Reader (Rear View)

A	Battery Cover	**F**	USB Port (manufacturer use only)
B	Battery Cover Release Buttons	**G**	Charging Connection
C	Barcode Scanner	**H**	Operation Indicator
D	UHF RFID Antenna	**I**	Handle
E	Trigger	**J**	Speaker

Stand (Recommended Cradle Mounting Option)

Note - The stand is the recommended cradle mounting option for the SurgiCount®+ System.

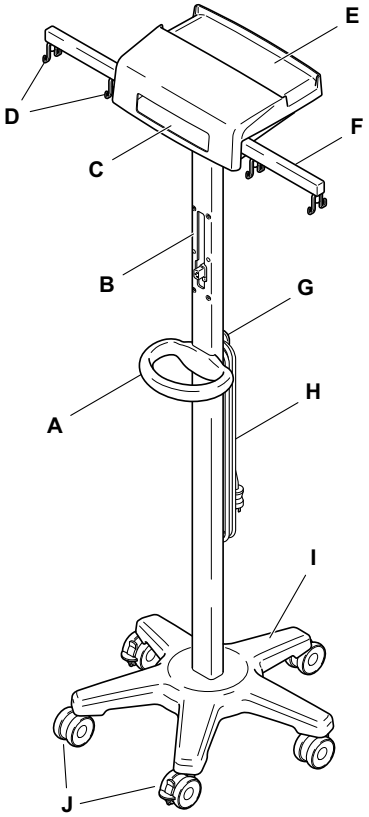


Figure 5 – Stand (Front View)

A	Handle	**F**	Arm (hinged)
B	Cradle Mounting Location	**G**	Power Cord Hook (quick release)
C	Storage Tray (sponge bags)	**H**	Power Cord
D	Arm Hooks	**I**	Stabilizing Base
E	Storage Tray (reader covers)	**J**	Swivel Casters (x3)
			Locking Casters (x2)

Alternative Cradle Mounting Options

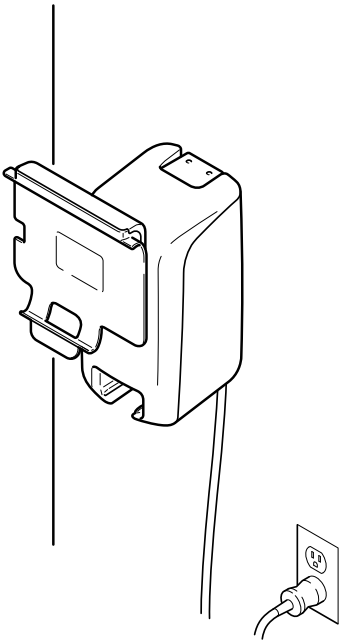


Figure 6 – Wall Mount

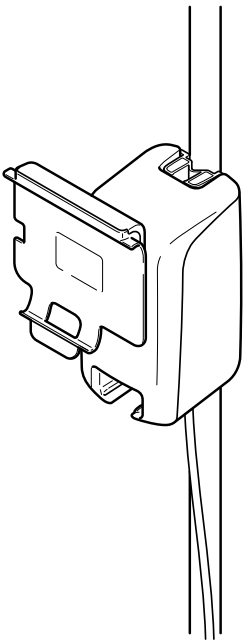


Figure 7 – Pole Mount

Getting Started

Before Use

1. Remove all the components from packaging material.
2. Inspect equipment for damage, see *Inspection and Maintenance* (page 19).

WARNING - When installing the cradle to a mounting option, always follow the installation guide provided with the equipment. Failure to comply may result in healthcare staff injury.

3. [Facility Maintenance Staff] – Refer to the applicable installation guide and complete the cradle installation, see *Documentation* (page 3).
4. Clean and disinfect the equipment before first use, see *Cleaning and Disinfection* (page 18).
5. Verify the power cord is connected to an electrical power receptacle.
6. Verify the tablet is ready for use. Refer to the tablet instructions for use as needed, see *Documentation* (page 3).
7. Dock the tablet, see *Interacting with the Cradle* (page 12).
8. *Remove the Reader Battery Cover* (page 14).
9. *Install the Reader Battery* (page 15).
10. *Install the Reader Battery Cover* (page 15).
11. *Dock the Reader* (page 13).
12. [Stand Configuration] – Load a carton of sponge bags and reader covers (disposables) into the stand storage trays, see *Interacting with the Stand* (page 17).

Using Your Product

Charging the System

CAUTION - Do not use the USB port to charge the reader. Failure to comply may result in damage to the device.

Note

- When connected to electrical power, the system will take approximately five (5) hours to fully charge. It is recommended to fully charge the system before each use.
- When disconnected from electrical power, a fully charged system will provide approximately ten (10) hours of use.
- System component charging status and battery life can be viewed within the Surgical Tablet software application user interface. For additional information, refer to the instructions for use for the applicable Surgical Tablet software application.

1. Verify the power cord is connected to an electrical power receptacle.
2. Dock the tablet, see *Interacting with the Cradle* (page 12).
3. *Dock the Reader* (page 13).
4. Verify the charging status and battery life of the system components.

Interacting with the Cradle

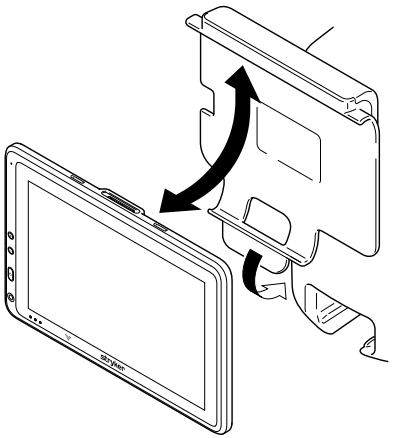


Figure 8 – Docking/Undocking the Tablet

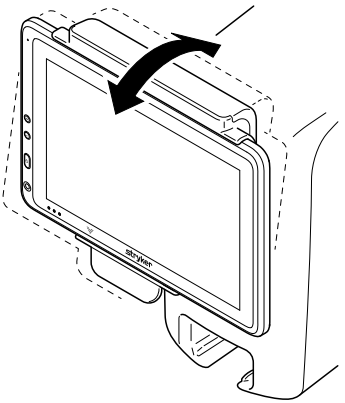


Figure 9 – Adjusting the Tilt Position

Reader Instructions

- *Docking and Undocking the Reader* (page 13).
- *Replacing the Reader Battery* (page 14).
- *Preparing the Reader for Sterile Use* (page 16).

Docking and Undocking the Reader

Dock the Reader

1. Rotate the reader and grasp the front of the device.
2. Insert the reader into the cradle (Figure 10).

Undock the Reader

1. Grasp the front of the reader.
2. Pull the reader out of the cradle (Figure 10).
3. Rotate the reader and grasp the handle of the device.

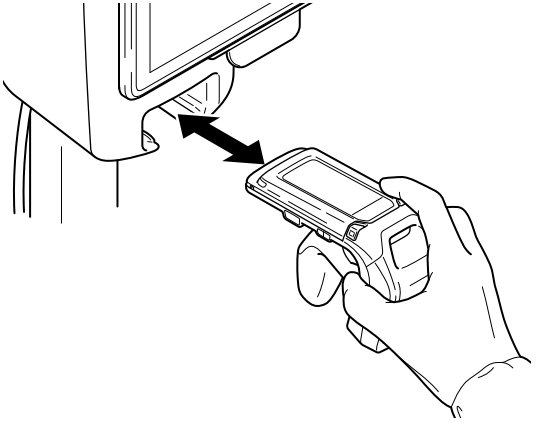


Figure 10 – Docking/Undocking the Reader

Replacing the Reader Battery

1. *Remove the Reader Battery Cover* (page 14).
2. *Remove the Reader Battery* (page 15).
3. *Install the Reader Battery* (page 15).
4. *Install the Reader Battery Cover* (page 15).

Remove the Reader Battery Cover

1. Press and hold the battery cover release buttons (Figure 11).
2. Slide the cover back and remove (Figure 12).

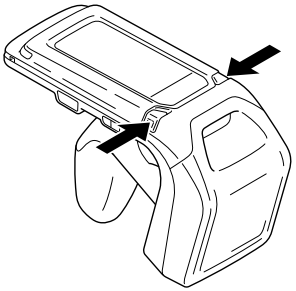


Figure 11 – Press and Hold Release Buttons

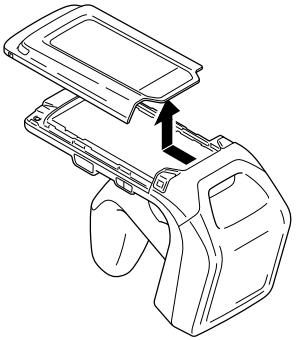


Figure 12 – Remove the Battery Cover

Remove the Reader Battery

1. Press in on the battery (Figure 13).
2. Remove the battery (Figure 14).

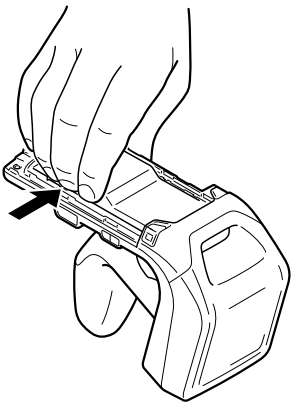


Figure 13 – Press in on the Battery

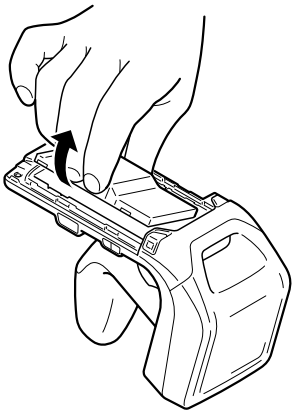


Figure 14 – Remove the Battery

Install the Reader Battery

1. Align and insert the battery tabs into the slots in the battery compartment (Figure 15).
2. Press down on the battery (Figure 16).

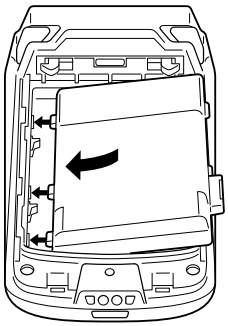


Figure 15 – Align and Insert the Battery

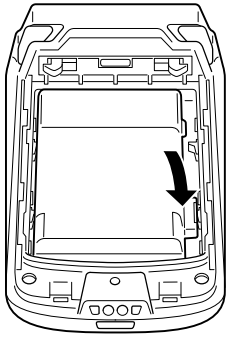


Figure 16 – Press Down on the Battery

Install the Reader Battery Cover

1. Align the battery cover over the battery.
2. Slide the battery cover forward until it locks into place.

Preparing the Reader for Sterile Use

1. [Circulating Nurse] – Open the reader cover sterile packaging.
2. [Circulating Nurse] – Aseptically transfer the reader cover to the sterile field.
3. [Scrub Technician] – Unfold the closed end of reader cover.
4. [Scrub Technician] – Place hands inside the reader cover cuff to create an opening.
5. [Circulating Nurse] – Aseptically transfer the reader into the opening of reader cover.
6. [Scrub Technician] – After the reader is placed inside of the reader cover, move hands to each end of the closure slide and allow the reader cover to fully extend.
7. [Scrub Technician] – Move the slider across to seal the reader cover.

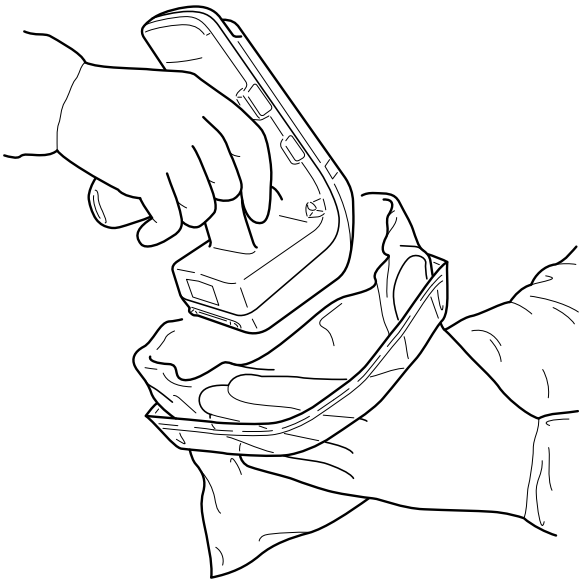


Figure 17 – Aseptic Transfer

Interacting with the Stand

WARNING - Always remove used sponge bags and fold the arms inward prior to transporting or positioning the stand on inclined surfaces.

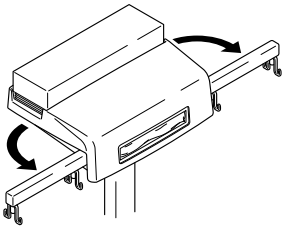


Figure 18 – Unfolding the Arms

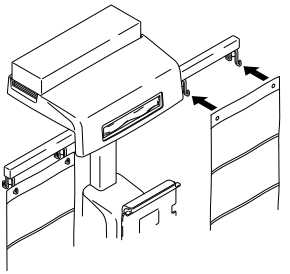


Figure 19 – Hanging Sponge Bags

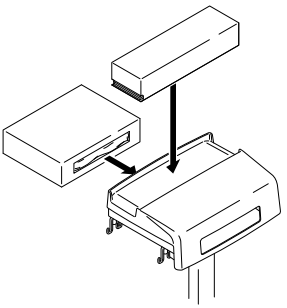


Figure 20 – Loading Disposables

CAUTION

- Always ensure the power cord is properly wrapped prior to transporting.
- Always lock the casters when the stand is stationary, and unlock prior to transporting.

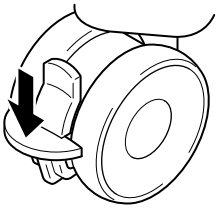


Figure 21 – Locking the Casters

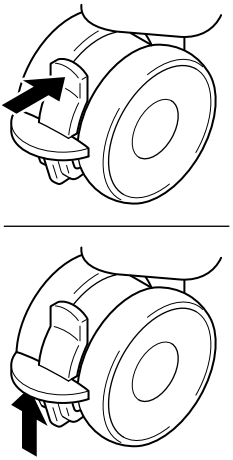


Figure 22 – Unlocking the Casters

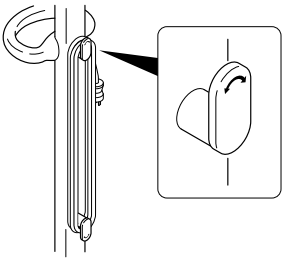


Figure 23 – Wrapping the Power Cord

After Use

Cleaning and Disinfection

WARNING

- Always clean and disinfect the equipment as indicated upon initial receipt and before each use. Failure to comply may cause infection and result in patient or healthcare staff injury.
- Always consult the instructions for use that accompanies accessories for product specific cleaning requirements.

CAUTION

- Do not immerse the equipment in liquid.
- Do not allow liquids or moisture to enter any electrical connection.
- Do not sterilize the equipment.
- Do not use solvents, lubricants, or other chemicals, including glutaraldehyde or similar chemical cleaners, unless otherwise specified.
- Use of unapproved disinfectants may cause damage to equipment.
- Do not clean the reader when the battery cover is removed.

Failure to comply may cause damage to the equipment or degrade performance.

Recommended Materials
PPE as recommended by the disinfectant manufacturer
Soft, lint-free cloth
United States Environmental Protection Agency (US EPA) registered disinfectant with a claim for activity against Hepatitis B. The following disinfectants have been validated for use on the exterior surfaces of the equipment: • Quaternary Ammonium Based – CaviCide (EPA #: 46781-6) • Clorox Healthcare® Bleach Germicidal Wipes (EPA Reg. # 67619-12)

1. Wipe all external surfaces of the equipment with a soft, lint-free cloth moistened with a non-abrasive, hospital disinfectant prepared according to the manufacturer's instructions. Clean surfaces until all visible soil is removed.
2. After removing all visible gross soil, use a clean cloth moistened with disinfectant and wipe all surfaces. Make sure all surfaces remain visibly wet at room temperature for at least the minimum time specified in the instructions supplied by the disinfectant manufacturer.
3. Remove any excess disinfectant solution using a soft, lint-free cloth moistened with water if required by the instructions supplied by the disinfectant manufacturer.

   CAUTION

   - Do not use an aerosol spray directly on the reader barcode scanner window. Failure to comply may result in damage to the device.
   - Do not let liquid pool around the reader barcode scanner window. Failure to comply may result in degraded performance.

4. Apply glass cleaner to a soft, lint-free cloth and clean the reader barcode scanner window.

References

Inspection and Maintenance

WARNING

- Upon initial receipt and before each use, inspect equipment for damage. Do not use any equipment if damage is apparent or the inspection criteria are not met.
- Do not disassemble, modify, service, or repair any equipment without the authorization of the manufacturer. Failure to comply may result in electric shock or fire. For assistance, contact Stryker.

Note

- Only biomedical equipment technicians trained and experienced in the maintenance of this reusable medical device should inspect and maintain this equipment.
- Always dispose of equipment properly, see *Disposal/Recycle* (page 21).

Upon initial receipt and before each use, inspect the following:

- Power cord for damage, bent pins, and cuts
- Cradle housing for damage and cracks
- Equipment damage or missing components
- Cradle vent holes for obstructions
- Equipment for corrosion, discoloration, pitting, cracked materials, or unacceptable deterioration on any external surfaces, including on-product labels
- [Stand Configuration] – Inspect casters for damage and obstructions
- [Stand Configuration] – Verify locking casters function properly

If inspection criteria are not met or damage is apparent, do not use the equipment and replace the damaged equipment, see *Service* (page 19).

Service

WARNING

- Do not disassemble, modify, service, or repair any equipment without the authorization of Stryker. Failure to comply may result in electric shock or fire. For assistance, contact Stryker.
- Always process contaminated equipment, before returning equipment to Stryker, see *Cleaning and Disinfection* (page 18). Stryker will not accept or process any contaminated equipment.

Note

- Maintenance documentation is only available to Stryker-authorized service personnel, for assistance contact Stryker.
- Always contact your local Stryker Service Center to obtain a repair purchase order before returning a product to the service center.

- To expedite returns, always include the following information with the returned equipment:
  - Contact name, address, phone number
  - Repair purchase order number
  - Part and serial number(s)
  - Detailed reason for return

Troubleshooting

WARNING - Do not disassemble, modify, service, or repair any equipment without the authorization of Stryker. Failure to comply may result in electric shock or fire. For assistance, contact Stryker.

Table 1 – Cradle Troubleshooting

Observation	Cause	Corrective Action
Erratic system behavior while equipment is in use.	Electrical noise and/or radio interference and/or high frequency (HF) surgical equipment is present.	Reorient or relocate electrical equipment to maximize the spatial distance between the equipment. Shielding the location may also be necessary.
		Connect the system and other operating room equipment to different hospital-grade electrical power receptacles on different branch circuits.
		Turn off all electrical equipment not in use in the operating room.
Significant reduction in battery run time of system.	System batteries are at end of life.	Contact Stryker.
Cradle is not charging.	Power cord connection issue.	Verify the power cord is properly connected to the hospital-grade electrical power receptacle.
	Electrical power not present.	Follow local healthcare facility protocol and verify electrical power is present at the hospital-grade electrical power receptacle.
	Cradle is damaged.	Contact Stryker.
Tablet is not charging.	Tablet is not fully docked in the cradle.	Verify the tablet is properly docked, see *Interacting with the Cradle* (page 12).

Observation	Cause	Corrective Action
	Tablet battery is at end of life.	Contact Stryker.
	Cradle is damaged.	Contact Stryker.
Tablet does not recognize the cradle.	Tablet is not fully docked.	Verify the tablet is properly docked, see *Interacting with the Cradle* (page 12).
	Cradle is damaged.	Contact Stryker.

Table 2 – Reader Troubleshooting

Observation	Cause	Corrective Action
Reader is not charging.	Reader is not fully docked.	Verify the reader is properly docked, see *Interacting with the Cradle* (page 12).
	Reader battery is at end of life.	Contact Stryker.
	Reader is damaged.	Contact Stryker.
	Cradle is damaged.	Contact Stryker.
Reader is continuously beeping while docked.	Reader battery is not installed or not installed properly.	Verify reader battery is properly installed, see *Replacing the Reader Battery* (page 14).
	Reader is damaged.	Contact Stryker.
Reader is not recognized by the tablet.	Reader is not fully docked.	Verify the reader is properly docked, see *Interacting with the Cradle* (page 12).
	Reader is damaged.	Contact Stryker.
	Cradle is damaged.	Contact Stryker.

Disposal/Recycle

WARNING - Always follow the current local recommendations and/ or regulations governing environmental protection and the risks associated with recycling or disposing of equipment.

WARNING - The SurgiCount+ Cradle and SurgiCount+ Reader use lithium–ion batteries. To reduce the risk of fire or burns, do not disassemble, crush, burn, or puncture the batteries.

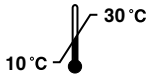
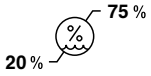
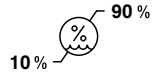
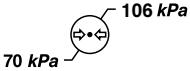
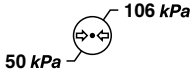
Specifications

SurgiCount+ Cradle		
REF:	0694-002-002	
Dimensions:	**Width:** 8.4 in **Height:** 13.6 in **Depth:** 8.6 in	
Weight:	5.5 lbs	
Ingress Protection:	IPX0	
Equipment Type:		Class II equipment with functional earth
Internal Power:	Li-ion 14.4 VDC ⎓	
External Power:	120VAC~60Hz, 0.9A	
Mode of Operation:	Continuous	
Frequency of Operation:	13.56 MHz	
RF Bandwidth:	13.553 MHz – 13.567 MHz	
Modulation:	ASK (Amplitude Shift Keying)	
RF Field Strength:	44.51 dBµV/m at 3 m	
Regulatory Compliance:		**Federal Communications Commission (FCC)** **FCC ID:** Q9R-0042 This device comples with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. Changes or modifications not expressly approved by Stryker Instruments could void your authority to operate this equipment.
		**California Energy Commission (CEC)** This device was tested and meets the California Code of Regulations - Appliance Efficiency Regulations certification requirements. For additional information, contact Stryker.
Product Safety Certification:		Intertek Group certification mark for United States. These products were tested and meet the audio/ video, information and communication technology equipment certification requirements. For additional information, contact Stryker.
	5018547	Conforms to UL STD 62368-1

SurgiCount+ Reader		
REF:	0694-002-005	
Dimensions:	**Width:** 3.1 in **Height:** 5.1 in **Depth:** 7.3 in	
Weight:	0.96 lbs	
Ingress Protection:	IPX0	
Equipment Type:	Class I equipment	
Internal Power:	Li-ion 4.2 VDC ⎓	
External Power:	5 VDC ⎓, 1.2A	
Mode of Operation:	Continuous	
UHF RFID	**Frequency of Operation:** 902.75 MHz – 927.25 MHz **Peak Output Power:** 981.748 mW **Modulation:** PR-ASK (Phase Reversal-Amplitude Shift Keying)	
Bluetooth	**Frequency of Operation:** 2400MHz to 2483.5MHz **Peak Output Power:** 3.428mW **Modulation:** BLE/GFSK	
Regulatory Compliance:	FC	**Federal Communications Commission (FCC)** **FCC ID**: UZ7RFD8500 This device comples with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. Changes or modifications not expressly approved by Stryker Instruments could void your authority to operate this equipment.
	BC	**California Energy Commission (CEC)** This device was tested and meets the California Code of Regulations - Appliance Efficiency Regulations certification requirements. For additional information, contact Stryker.
Product Safety Certification:	c UL us LISTED	Underwriters Laboratories (UL) certification mark for United States. These products were tested and meet the audio/video, information and communication technology equipment certification requirements. For additional information, contact Stryker. **Note -** The barcode LED is classified as “EXEMPT RISK GROUP” according to IEC 62471.

SurgiCount+ Stand	
REF:	0694-002-001
Dimensions:	**Width:** 24.0 in **Height:** 70.8 in **Depth:** 24.0 in
Weight:	52.6 lbs (without the cradle installed)

Environmental Conditions

Environmental Condition	Operation	Storage and Transport
Temperature:		
Relative Humidity:		
Atmospheric Pressure:		

Electromagnetic Compatibility

WARNING

- Avoid locating equipment adjacent to the SurgiCount®+ System. If such a configuration is necessary, verify normal operation of both the SurgiCount®+ System and the adjacent equipment during use.
- Always maintain a minimum separation distance of 6 inches [15 cm] from an in-use pacemaker and the UHF RFID antenna of the SurgiCount®+ Reader while in use. Failure to comply may cause interference with the pacemaker.

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration - Electromagnetic Emissions</th></tr>
<tr><td colspan="3">This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of this equipment should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>FCC</td><td>Part 15</td><td>WARNING - Always maintain a minimum separation distance of 9 inches [23 cm] from the head and torso of a person and the UHF RFID antenna of the SurgiCount®+ Reader while in use. Failure to comply may cause FCC RF exposure limits to be exceeded.
The SurgiCount®+ System complies with FCC regulations for conducted and radiated emissions under FCC Part 15.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 2</td><td>WARNING - The SurgiCount®+ System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class A</td><td rowspan="3">WARNING - This equipment is intended for use in a professional healthcare facility environment. This equipment may cause radio interference or may disrupt the operation of other nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the SurgiCount®+ System or shielding the location.</td></tr>
<tr><td>Harmonic Emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations/ Flicker Emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product 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, ±4, ±8, ±15 kV Air ±8 kV Contact	±2, ±4, ±8, ±15 kV Air ±8 kV Contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 10%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV at 100 kHz repetition frequency for power supply lines	±2 kV at 100 kHz repetition frequency for power supply 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	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°	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°	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m at 60 Hz	30 A/m at 60 Hz	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Conducted RF IEC 61000-4-6	3 Vrms150 kHz to 80 MHz outside ISM bands 80% AM at 1 kHz 6 Vrms150 kHz to 80 MHz in ISM bands 80% AM at 1 kHz	3 Vrms150 kHz to 80 MHz outside ISM bands 80% AM at 1 kHz 6 Vrms150 kHz to 80 MHz in ISM bands 80% AM at 1 kHz	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 SurgiCount®+ System 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[1] should be less than the compliance level in each frequency range[2]. 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 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	

Note

- At 80 MHz and 800 MHz the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[1]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 SurgiCount®+ System is used exceeds the applicable RF compliance level above, the SurgiCount®+ System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SurgiCount®+ System.

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

Manufactured For:
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